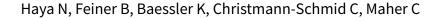


**Cochrane** Database of Systematic Reviews

# Perioperative interventions in pelvic organ prolapse surgery (Review)



Haya N, Feiner B, Baessler K, Christmann-Schmid C, Maher C. Perioperative interventions in pelvic organ prolapse surgery. *Cochrane Database of Systematic Reviews* 2018, Issue 8. Art. No.: CD013105. DOI: 10.1002/14651858.CD013105.

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#### [Intervention Review]

# Perioperative interventions in pelvic organ prolapse surgery

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#### **ABSTRACT**

### **Background**

Pelvic organ prolapse (POP) affects as many as 50% of parous women, with 14% to 19% of women undergoing a surgical correction. Although surgery for the treatment of POP is common, limited supportive data can be found in the literature regarding the preoperative and postoperative interventions related to these procedures. The main goal of perioperative interventions is to reduce the rate of adverse events while improving women's outcomes following surgical intervention for prolapse. A broad spectrum of perioperative interventions are available, and although the benefits of interventions such as prophylactic antibiotics before abdominal surgery are well established, others are unique to women undergoing POP surgeries and as such need to be investigated separately.

# **Objectives**

The aim of this review is to compare the safety and effectiveness of a range of perioperative interventions versus other interventions or no intervention (control group) at the time of surgery for pelvic organ prolapse.

#### **Search methods**

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In Process, ClinicalTrials.gov, WHO ICTRP, handsearching of journals and conference proceedings (searched 30 November 2017), and reference lists of relevant articles. We also contacted researchers in the field.

# **Selection criteria**

We included randomised controlled trials (RCTs) of women undergoing surgical treatment for symptomatic pelvic organ prolapse that compared a perioperative intervention related to pelvic organ prolapse surgery versus no treatment or another intervention.

# **Data collection and analysis**

We used standard methodological procedures recommended by Cochrane. Our primary outcomes were objective failure at any site and subjective postoperative prolapse symptoms. We also measured adverse effects, focusing on intraoperative blood loss and blood transfusion, intraoperative ureteral injury, and postoperative urinary tract infection.



#### **Main results**

We included 15 RCTs that compared eight different interventions versus no treatment for 1992 women in five countries. Most interventions were assessed by only one RCT with evidence quality ranging from very low to moderate. The main limitation was imprecision, associated with small sample sizes and low event rates.

Pelvic floor muscle training (PFMT) compared with no treatment (three RCTs) - peri-operative intervention

The simplest of the PFMT programmes required women to attend six perioperative consultations in the three months surrounding prolapse surgery. Trial results provided no clear evidence of a difference between groups in objective failure at any site at 12 to 24 months (odds ratio (OR) 0.93, 95% confidence interval (CI) 0.56 to 1.54; two RCTs, 327 women; moderate-quality evidence). With respect to awareness of prolapse, findings were inconsistent. One RCT found no evidence of a difference between groups at 24 months (OR 1.07, 95% CI 0.61 to 1.87; one RCT, 305 women; low-quality evidence), and a second small RCT reported symptom reduction from the Pelvic Organ Prolapse Symptom Questionnaire completed by the intervention group at 12 months (mean difference (MD) -3.90, 95% CI -6.11 to -1.69; one RCT, 27 women; low-quality evidence). Researchers found no clear differences between groups at 24-month follow-up in rates of repeat surgery (or pessary) for prolapse (OR 1.92, 95% CI 0.74 to 5.02; one RCT, 316 women; low-quality evidence).

#### Other interventions

Single RCTs evaluated the following interventions: preoperative guided imagery (N = 44); injection of vasoconstrictor agent at commencement of vaginal prolapse surgery (N = 76); ureteral stent placement during uterosacral ligament suspension (N = 91); vaginal pack (N = 116); prophylactic antibiotics for women requiring postoperative urinary catheterisation (N = 159); and postoperative vaginal dilators (N = 60).

Two RCTs evaluated bowel preparation (N = 298), and four RCTs assessed the method and timing of postoperative catheterisation (N = 514) - all in different comparisons.

None of these studies reported our primary review outcomes. One study reported intraoperative blood loss and suggested that vaginal injection of vasoconstrictors at commencement of surgery may reduce blood loss by a mean of about 30 mL. Another study reported intraoperative ureteral injury and found no clear evidence that ureteral stent placement reduces ureteral injury. Three RCTs reported postoperative urinary tract infection and found no conclusive evidence that rates of urinary tract infection were influenced by use of a vaginal pack, prophylactic antibiotics, or vaginal dilators. Other studies did not report these outcomes.

#### **Authors' conclusions**

There was a paucity of data about perioperative interventions in pelvic organ prolapse surgery. A structured programme of pelvic floor muscle training before and after prolapse surgery did not consistently demonstrate any benefit for the intervention; however, this finding is based on the results of two small studies. With regard to other interventions (preoperative bowel preparation and injection of vasoconstrictor agent, ureteral stent placement during uterosacral ligament suspension, postoperative vaginal pack insertion, use of vaginal dilators, prophylactic antibiotics for postoperative catheter care), we found no evidence regarding rates of recurrent prolapse and no clear evidence that these interventions were associated with clinically meaningful reductions in adverse effects, such as intraoperative or postoperative blood transfusion, intraoperative ureteral injury, or postoperative urinary tract infection.

### PLAIN LANGUAGE SUMMARY

# Perioperative interventions in pelvic organ prolapse surgery

A wide variety of interventions are undertaken at prolapse surgeries; however data are lacking and consensus has not been reached on the efficacy of these interventions. The most reliable evidence is likely to come from randomised controlled trials, and this is the basis for this review.

#### **Review questions**

- Which perioperative interventions reduce rates of intraoperative and postoperative complications?
- · Which perioperative interventions improve outcomes of surgery performed for pelvic organ prolapse?

# Background

Surgery for pelvic organ prolapse is commonly performed and a variety of perioperative interventions are undertaken to improve outcomes of surgery.

# **Study characteristics**

Cochrane review authors evaluated randomised controlled trials (RCTs) that compared prolapse surgery with and without any perioperative (before, during, or after) interventions. The evidence is current to 30 November 2017. Reviewers included 15 trials that



evaluated eight different interventions related to prolapse surgery. Although primary outcomes of the review were objective failure (recurrence of prolapse on examination) and awareness of prolapse, reviewers also measured adverse effects, focusing on intraoperative blood loss, intraoperative ureteral injury, postoperative urinary tract infection, and repeat surgery.

### **Key results**

Reviewers found very little evidence on perioperative interventions in pelvic organ prolapse surgery. Few trials reported primary outcomes. A structured programme of pelvic floor muscle training before and after surgery did not consistently demonstrate any benefit for the intervention. With regard to other preoperative interventions, neither bowel preparation nor detailed preoperative mapping demonstrated significant benefit when compared to usual care.

Intraoperative interventions such as injection of a vasoconstrictor agent, ureteral stent placement during uterosacral ligament suspension, or placement of a vaginal pack did not demonstrate benefit for reduced blood loss or rate of urinary tract infection or injury to the ureter.

Vaginal packing postoperatively did not reduce the rate of haematoma (collection of blood) when compared to prolapse surgery without packing in a single trial. The rate of postoperative urinary tract infection was not reduced by use of a vaginal pack, prophylactic antibiotics, or vaginal dilators.

# Quality of the evidence

The quality of the evidence ranged from very low to moderate. The main limitation was imprecision, associated with small sample sizes and low event rates.



Summary of findings for the main comparison. Pelvic floor muscle training before and after prolapse surgery compared to no training in pelvic organ prolapse surgery

Pelvic floor muscle training before and after prolapse surgery compared to no training in pelvic organ prolapse surgery

Patient or population: women undergoing pelvic organ prolapse surgery

Setting: hospital, in USA and UK

**Intervention:** pelvic floor muscle training before and after prolapse surgery

**Comparison:** usual perioperative care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of partici- pants	Quality of the evidence	Comments	
	Risk with usual perioperative care	Risk with pelvic floor mus- cle training before and af- ter prolapse surgery	(33 /0 Cl)	(studies)	(GRADE)		
Objective failure at any site: at 12 to 24 months	249 per 1000	235 per 1000 (156 to 337)	OR 0.93 (0.56 to 1.54)	327 (2 studies)	⊕⊕⊕⊝ MODERATE <sup>a</sup>	One study followed up only 10/57 and reported no events at 12 months. Not downgraded for risk of bias, as the other much bigger study was at low risk of bias for this outcome in all relevant domains	
Subjective awareness of pro- lapse: Pelvic organ prolapse Symptom score (POP-SS) at 12 months	Mean score in control group 6.4 points	Mean score in the intervention group 2.5 points. The mean POPSS score was 3.9 points lower (favourable) in the intervention group  (6.11 to 1.69 points lower)		48 (1 study)	⊕⊕⊝⊝ LOWa,b	POPSS includes 7 items, each with a 0 to 5 range. Total score range is 0 to 28 points. A higher score denotes more symptoms.	
Subjective awareness of pro- lapse: feeling of bulge at 24 months	195 per 1000	206 per 1000 (129 to 311)	OR 1.07 (0.61 to 1.87)	305 (1 study)	⊕⊕⊙⊝ LOWa,b		
Intraoperative blood loss	No data were available.						
Intraoperative ureteral injury	No data were available.						

Postoperative urinary tract infection	No data were ava	No data were available.				
Repeat surgery (or pessary) for recurrent prolapse	43 per 1000	79 per 1000 (32 to 183)	OR 1.92 (0.74 to 5.02)	316 (1 study)	⊕⊕⊝⊝ LOW <sup>c</sup>	

<sup>\*</sup>The risk in the intervention group (and its 95% confidence interval) is based on the mean risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; OR: odds ratio; POP-SS: Pelvic Organ Prolapse Symptom Score.

# **GRADE Working Group grades of evidence.**

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

**Moderate quality:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

<sup>a</sup>Downgraded one level for serious imprecision: wide confidence interval compatible with benefit, harm, or no effect from the intervention.

<sup>b</sup>Downgraded one level for serious risk of bias associated with subjective outcome measure: study not blinded.

<sup>c</sup>Downgraded two levels for very serious imprecision: very wide confidence interval compatible with benefit, harm, or no effect from the intervention.



#### BACKGROUND

Pelvic organ prolapse (POP) is common and is seen on examination in 40% to 60% of parous women (Handa 2004; Hendrix 2002). The annual aggregated rate of associated surgery in the USA is in the range of 10 to 30 per 10,000 women as reported by Brubaker 2002, and is 14 per 10,000 women in countries of the Organisation for Economic Cooperation and Development (OECD) (Haya 2015). Procedures can be separated broadly into obliterative (colpocleisis) or reconstructive vaginal interventions, with the latter most commonly undertaken. Reconstructive interventions seek to repair the prolapse by plicating the damaged connective tissue or fascia with sutures (colporrhaphy) and resuspending the uterus (hysteropexy) or vagina (colpopexy) to firm supporting structures such as the uterosacral (uterosacral colpopexy) or sacrospinous (sacrospinous colpopexy) ligaments, or the pubic bone or sacrum (sacral colpopexy). Women with uterine prolapse may be offered hysterectomy or a uterine fixating procedure. Surgery can be performed transvaginally or abdominally with native tissue repair or graft utilisation. Abdominal procedures can be performed via laparotomy or via conventional laparoscopic or robotically assisted laparoscopic techniques. Other reviews have evaluated specific surgical interventions. The individual woman's surgical history and goals, as well as her risks for adverse events, prolapse recurrence, and de novo symptoms, affect surgical planning and choice of procedure. In addition to this, a broad spectrum of perioperative interventions are being undertaken to improve the outcomes of prolapse surgery. Some perioperative interventions such as prophylactic antibiotics are used broadly in other fields of surgery; however many of these interventions are unique to women who undergo POP surgeries and therefore need to be investigated separately. The aim of this review is to determine the safety and effectiveness of different perioperative interventions that are undertaken at the time of prolapse surgery.

# **Study characteristics**

We evaluated data from randomised controlled trials that examined outcomes of perioperative interventions undertaken during pelvic organ prolapse surgery.

# **Description of the condition**

Pelvic organ prolapse is described as the descent of one or more pelvic organs (uterus, vagina, bladder, or bowel). Types of prolapse include:

- upper vaginal prolapse (i.e. uterus, vaginal vault (post hysterectomy when the top of the vagina drops down));
- anterior vaginal wall prolapse (i.e. cystocoele (bladder descends), urethrocoele (urethra descends), paravaginal defect (pelvic fascia defect)); and
- posterior vaginal wall prolapse (i.e. enterocoele (small bowel descends), rectocoele (rectum descends), perineal deficiency).

A woman can present with prolapse at one or more sites. The origin of pelvic organ prolapse (POP) is complex and multi-factorial. Possible risk factors include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakness of the pelvic floor, ageing, hysterectomy, menopause, and factors associated with chronically raised intra-abdominal pressure (Bump 1998; Gill 1998; MacLennan 2000). Women with prolapse commonly have a variety of pelvic floor symptoms, only

some of which are directly related to the prolapse. Generalised symptoms of prolapse include pelvic heaviness, bulge, lump or protrusion coming down from the vagina, a dragging sensation in the vagina, and backache. Symptoms of bladder, bowel, or sexual dysfunction are frequently present. For example, women may need to manually reduce the prolapse to aid urinary voiding or defecation. These symptoms may be directly related to the prolapsed organ (poor urinary stream when a cystocoele is present or obstructed defecation when a rectocoele is present). Symptoms may also be independent of the prolapse, for example, overactive bladder symptoms (urinary frequency and urgency) when a cystocoele is present, or constipation with the presence of a rectocoele. The complexity of symptoms contributes significantly to the difficulty involved in evaluating postoperative outcomes following prolapse surgery. Clear evaluation of any perioperative intervention is required to ensure that the intervention is effective and beneficial. A wide variety of surgical interventions are performed for treatment of prolapse.

### **Description of the intervention**

Treatment of prolapse depends on the severity of the prolapse, its symptoms, the woman's general health, surgeon preference and capabilities, and the hospital environment in which the intervention is to be undertaken. We have not included trials that reviewed non-prolapse-specific interventions such as treatment of postoperative nausea and pain and use of perioperative antibiotics - all of which have been evaluated in relation to surgery in general. Options available for perioperative intervention are divided into preoperative, intraoperative, postoperative, and perioperative options, and include the following.

- · Perioperative
  - \* Perioperative pelvic floor training
- Preoperative
  - Preoperative education, guided imagery (GIM): patients in the intervention group were asked to listen to a 15minute audio CD daily (the CD was developed by a trained behaviouralist and detailed the day of surgery events and expectations using both GIM and relaxation techniques)
  - \* Preoperative bowel preparation: bowel preparation in the abdominal or pelvic area is optionally recommended by surgeons (Miettinen 2000). Patients are instructed to use oral bowel softeners or enema in preparation to eliminate faecal matter from the intestinal tract to allow better visualisation of the surgical field while reducing bowel-related surgical complications
- Intraoperative
  - \* Vaginal injection of vasoconstrictor: hydrodissecton (submucosal injection) is utilised to facilitate dissection of the vaginal mucosa from the underlying fascia and to minimise blood loss
  - \* Ureteral stent during uterosacral ligament suspension: a flexible plastic hollow tube placed in the ureter is assumed to help surgeons identify the ureter and avoid ureteral injury while placing sutures in the uterosacral ligaments for vaginal vault or uterine fixation
- Postoperative
  - \* Vaginal packing: following vaginal prolapse surgery, a wide cotton gauze is packed tightly into the vaginal cavity; it is removed on the morning of postoperative day 1. Possible benefits include reduced blood loss and decreased rates



of postoperative submucosal haematoma formation and vaginal adhesions

- \* Postoperative catheterisation care: urinary retention is one of the best known early postoperative complications reported in women undergo POP procedures; it may lead to urinary tract infection and urinary voiding dysfunction in cases of bladder overdistension. Women usually are treated with a transurethral indwelling catheter or use intermittent self-catheterisation until normal voiding is restored. Prophylactic antibiotics may be used to minimise the risk for urinary tract infection
- \* Postoperative vaginal dilators: vaginal dilators are commonly used as a conservative method to increase vaginal diameter and length. Vaginal stricture is an adverse result of vaginal prolapse procedures and can negatively affect sexual function by reducing vaginal calibre and length and producing scarring that may lead to de novo dyspareunia

# How the intervention might work

- Perioperative intervention
  - \* Pelvic floor muscle training increases muscle strength and support, thereby helping to reduce rates of recurrent prolapse and incontinence
- Preoperative interventions
  - \* Preoperative patient education may increase patient preparedness and reduce anxiety before surgery and postoperatively; overall it may improve the patient's experience
  - \* Bowel preparation may decrease the bowel load and allow better clearance of the surgical field, avoiding constipation and straining In the early postoperative period
- Intraoperative interventions
  - \* Vaginal injection with a vasoconstrictor may increase vasoconstriction and decrease intraoperative blood loss, reduce postoperative blood transfusion, and improve clearance of the surgical field
  - \* Use of a ureteral stent during uterosacral ligament suspension may help the surgeon identify the ureters and avoid ureteral injury
- Postoperative interventions
  - Vaginal pack may reduce postoperative adverse events such as pelvic haematoma and vaginal infection; however it may be associated with increased pain
  - Different methods of postoperative catheter care may reduce the risk for urinary tract infection, accelerate patient mobilisation, and reduce hospital stay
  - Vaginal dilators may decrease the incidence of postoperative adverse effects such as dyspareunia caused by vaginal strictures and scarring

#### Why it is important to do this review

A wide variety of perioperative interventions can be undertaken at prolapse surgery; however data are lacking and consensus has not been reached on the efficacy of these interventions. The safety of some perioperative interventions remains to be proven, and other interventions consume the time of both patients and medical staff. The most reliable evidence is likely to come from randomised controlled trials, and this is the basis for this review. The aim of this

review is to help define optimal practice while highlighting topics in need of further research.

# **OBJECTIVES**

To compare the safety and effectiveness of a range of perioperative interventions versus other interventions or no intervention (control group) at the time of surgery for pelvic organ prolapse.

#### **METHODS**

### Criteria for considering studies for this review

# Types of studies

We planned to include randomised controlled trials (RCTs) in which participants in at least one arm received a perioperative intervention related to pelvic organ prolapse surgery with no limitations on age or parity. We excluded non-randomised studies (e.g. studies with evidence of inadequate sequence generation such as alternate days or patient numbers), as they are associated with high risk of bias.

#### Types of participants

We planned to include adult women undergoing surgical treatment for symptomatic pelvic organ prolapse.

Pelvic organ prolapse includes:

- anterior vaginal wall prolapse (cystocoele, urethrocoele, paravaginal defect);
- posterior vaginal wall prolapse (enterocoele, rectocoele, perineal deficiency);
- apical prolapse; and
- · uterine prolapse.

# Types of interventions

We sought to include trials providing any surgery-specific perioperative intervention related to abdominal or vaginal surgery for pelvic organ prolapse. Items used for comparison included no treatment (control group) or a different intervention. Both groups were required to undergo the same surgical procedures for prolapse. We excluded trials of interventions that have been previously assessed in other Cochrane reviews such as analgesia, antiemetics, and vaginal oestrogen.

Interventions included the following.

#### Perioperatrive

\* Perioperative pelvic floor training

# Preoperative

- \* Preoperative education
- Bowel preparation before prolapse surgery

# Intraoperative

- Submucosal injection of vasoconstrictor agent at commencement of vaginal prolapse surgery
- \* Ureteral stent placement during uterosacral ligament suspension



# Postoperative

- \* Vaginal pack insertion after pelvic organ prolapse surgery
- \* Postoperative catheter care (indwelling catheter, clean intermittent catheter, and suprapubic catheter) and different timing of catheter removal
- Use of vaginal dilators postoperatively

#### Types of outcome measures

#### **Primary outcomes**

#### Subjective primary outcome

- Awareness of prolapse assessed by a variety of pelvic floor questionnaires
  - \* Pelvic Floor Distress Inventory (PFDI)

*	Combination of three questionnaires (with scores ranging
	from 0 to 100)
	☐ Pelvic Organ Prolapse Distress Inventory (POPDI)
	☐ Urinary Distress Inventory (UDI)
	☐ Colorectal-Anal Distress Inventory (CRADI) and/or Pelvic
	Organ Prolapse Symptom Score (POP-SS) - a self-
	completed seven-item questionnaire scored from 0 to 28,
	with higher scores indicating worse symptoms (Hagen

### **Objective primary outcomes**

2009)

- Objective failure at any site
- Vaginal prolapse scored by three compartments
  - \* Anterior vaginal wall
  - \* Posterior vaginal wall
  - \* Vaginal vault or prolapse of uterus
    - ☐ The hymen is a landmark by which prolapse staging is determined: hymen or beyond anterior compartment, hymen or beyond posterior compartment, hymen or beyond apical compartment
- Any stage 2 or greater prolapse as defined by Pelvic Organ Prolapse Quantification (POPQ) (the most distal portion of the prolapse is ≤ 1 cm proximal or distal to the hymnal plane)

# Secondary outcomes

# **Subjective secondary outcomes**

- Surgical field clearance, intraoperative assessment of operative field, intraoperative stooling
- Patient satisfaction: Global Impression of Improvement (PGI-I)

   participants were asked to choose one of seven options that represents their impression of improvement (1 = very much better, 7 = very much worse)
- Adverse events assessed immediately or up to three months post surgery
  - \* Vaginal atrophy (vaginal pallor, petechiae, friability, and dryness graded on a 4-point scale from none to severe)
- Postoperative bowel function
  - \* Mean time to first bowel movement≤
  - \* Faecal urgency and incontinence
  - \* Pain on first bowel movement
- · Patient satisfaction related to bowel preparation

#### Quality of life measures

- · General health Short Form Health Survey (SF-12)
  - \* Form includes two questions concerning physical functioning; two questions on role limitations due to physical health problems; one question on bodily pain; one question on general health perceptions; one question on vitality (energy/fatigue); one question on social functioning; two questions on role limitations due to emotional problems; and two questions on general mental health (psychological distress and psychological well-being)
  - \* Scores < 50 are considered to show better than average health
  - \* Scores ≥ 50 represent less than average quality of life as a result of the participant's medical condition (Appendix 1)
- Postoperative de novo dyspareunia assessed by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) with main focus on Question 5, which represents how the participant feels about her sex life (I feel frustrated by my sex life/I feel sexually inferior because of my incontinence and/or prolapse/I feel angry because of the impact that incontinence and/or prolapse has on my sex life)
  - Score can be between 3 and 12
     The lower the score, the better the sex life
- Sexual function post POP procedure
  - PISQ-12 Questionnaire (score range 0 to 48 with high scores indicating better overall function)
- Patient perioperative anxiety
  - \* Effect of preoperative guided imagery for women undergoing pelvic floor reconstructive procedures on patients' anxiety, preparedness, and satisfaction
  - \* Validated State-Trait Anxiety linventory (STAI), Pelvic Floor Distress Inventory (PFDI), and Patients' Global Impression of Improvement (PGI-I) utilised to identify differences between GIM and usual care groups

# **Objective secondary outcomes**

- Adverse events assessed immediately or up to three months post surgery
  - Intraoperative injury to bladder, ureter (ureteral kinking or obstruction)
  - Intraoperative or postoperative blood transfusion
     Blood loss assessed by blood loss estimation in mL, haemodynamic measures
  - Granulation tissue three months post vaginal surgery (granulation tissue is defined as the presence of red or pink fleshy tissue, most often along the suture line and usually causing vaginal bleeding and vaginal discharge)
  - Postoperative infection, urinary tract infection (assessed by mid-stream urine culture), vaginal infection (assessed by high vaginal swab)
  - \* Postoperative pelvic haematoma



Ac	lverse events assessed after three months post surgery
*	Postoperative treatment for urinary incontinence  Conservative (pelvic floor muscle training, pessary for urinary incontinence, periurethral bulking injection, iIntravesical botulinum toxin injection, neuromodulation)
	☐ Operative
*	Repeat surgery for prolapse  Conservative (pessary)
	☐ Operative
*	Postoperative treatment for urinary incontinence  Conservative (pelvic floor muscle training, pessary for urinary incontinence, periurethral bulking injection, intravesical botulinum toxin injection, neuromodulation)
	☐ Operative
*	Pelvic floor muscle (PFM) power or strength assessed by Brink grading system (evaluates three pelvic floor muscle

#### **Health service outcomes**

• Length of stay (days)

#### Search methods for identification of studies

contraction variables) (Brink 1994; Appendix 2)

We did not impose any language or other limits on any of the searches which are detailed below.

#### **Electronic searches**

This review has drawn on the search strategy developed for the Cochrane Incontinence Group. We identified relevant trials from the Cochrane Incontinence Specialised Trials Register. The Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, CINAHL, ClinicalTrials.gov, WHO ICTRP, UK Clinical Research Network Portfolio and handsearching of journals and conference proceedings.

The Incontinence Group Specialised Register was searched on 30 November 2017 using the Group's own keyword system. We used the following search terms:

 $\begin{tabular}{lll} $$ (\{design.cct^*\} & AND & (\{topic. prolapse^*\}) & AND & (\{intvent.surg^*\}) &$ 

Review authors also undertook searches of healthcare-related bibliographic databases (most recent, August 2017).

# **Searching other resources**

We handsearched conference proceedings for the International Urogynecology Society (IUGA) and the International Continence Society (ICS) for podium presentations from 2012 to 2017. We searched the reference lists of relevant articles and contacted researchers in the field.

# Data collection and analysis

We used standard methodological procedures as expected by Cochrane.

# **Selection of studies**

Two review authors (NH and CM) independently assessed titles and, if available, abstracts of all possibly eligible studies to ensure

compliance with review inclusion criteria. Then at least two review authors (from NH, BF, and CM) independently assessed full reports of each study likely to be eligible. We have listed excluded studies along with the reasons for their exclusion in the Characteristics of excluded studies table.

### **Data extraction and management**

At least two review authors (NH and CM) independently extracted data and details of comparisons made to ensure accuracy. We resolved discrepancies by discussion or by referral to a third party (BF). When trial data were not reported adequately, we attempted to acquire the necessary information from study authors.

#### Assessment of risk of bias in included studies

Two review authors (NH and CM) independently assessed the included studies for risk of bias using the Cochrane risk of bias assessment tool to assess selection (random sequence generation and allocation concealment), performance (blinding of participants and personnel), detection (blinding of outcome assessors), attrition (incomplete outcome data), reporting (selective reporting), and other bias (Higgins 2011a). We resolved disagreements by discussion or by consultation with a third review author. We described all judgements fully and presented our conclusions in the 'Risk of bias' tables.

#### Measures of treatment effect

For dichotomous data, we used numbers of events in control and intervention groups of each study to calculate Mantel-Haenszel odds ratios (ORs). For continuous data, if all studies reported exactly the same outcomes, we calculated mean differences (MDs) between treatment groups. If similar outcomes had been reported on different scales, we would have calculated standardised mean differences (SMDs). We presented 95% confidence intervals (CIs) for all outcomes. We compared the magnitude and direction of effect reported by studies with how they are presented in the review and accounted for legitimate differences.

# Unit of analysis issues

We conducted the primary analyses per woman randomised.

# Dealing with missing data

We analysed the data on an intention-to-treat basis as far as possible, and we attempted to obtain missing data from the original trial reports. When we could not obtain these data, we analysed only available data.

### **Assessment of heterogeneity**

We considered whether the clinical and methodological characteristics of included studies were sufficiently similar for meta-analysis to provide a clinically meaningful summary. We assessed statistical heterogeneity by determining the value of I<sup>2</sup>. We agreed that an I<sup>2</sup> measurement greater than 50% indicated substantial heterogeneity (Higgins 2003).

#### **Assessment of reporting biases**

In view of the difficulty involved in detecting and correcting for publication bias and other reporting biases, review authors aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and by staying alert for duplication of



data. If we included more than 10 studies in the same analysis, we planned to construct a funnel plot to assess publication bias.

#### **Data synthesis**

We systematically reviewed the data from RCTs evaluating perioperative interventions in pelvic organ prolapse surgeries and, when feasible, we planned to perform a meta-analysis of the data using a fixed-effect model to determine the safety and efficacy of the following interventions versus no intervention.

#### Preoperative

- \* Preoperative education
- \* Bowel preparation before prolapse surgery

#### Intraoperative

- Infiltration of vasoconstrictor agent at commencement of vaginal prolapse surgery
- \* Ureteral stent placement during uterosacral ligament suspension

#### Postoperative

- \* Vaginal pack insertion after pelvic organ prolapse surgery
- \* Postoperative catheter care (indwelling catheter/clean intermittent catheter and suprapubic catheter, different timing of catheter removal, prophylactic antibiotics during catheter utilisation)
- \* Utilisation of vaginal dilators

# Perioperatrive

\* Perioperative pelvic floor training

# Subgroup analysis and investigation of heterogeneity

When data were available, we planned to conduct subgroup analyses to gather separate evidence within the above subgroups. Had we detected substantial heterogeneity, we planned to explore possible explanations by performing sensitivity analyses. We took statistical heterogeneity into account when interpreting study results, especially if we noted any variation in the direction of effect.

# **Sensitivity analysis**

We planned to conduct sensitivity analyses for the primary outcomes to determine whether the conclusions were robust to arbitrary decisions made regarding eligibility and analysis. These analyses included consideration of whether review conclusions would have differed if:

- eligibility had been restricted to studies without high risk of bias (i.e. studies at high or unclear risk of selection bias, or at high risk of bias in any domain);
- a random-effects model had been adopted; or
- the summary effect measure had been relative risk rather than odds ratio.

# Overall quality of the body of evidence - 'Summary of findings' table

We prepared a 'Summary of findings' table using GRADEpro software (GRADEproGDT 2015), along with Cochrane methods (Higgins 2011). This table evaluated the overall quality of the body of evidence for the following review outcomes - objective failure at any site, awareness of prolapse, intraoperative and postoperative blood transfusion and blood loss, intraoperative ureteral injury, postoperative urinary tract infection, and repeat surgery or pessary

(for recurrent prolapse) for the main review comparison (pelvic floor muscle training before and after prolapse surgery vs no treatment). We assessed the quality of the evidence using GRADE criteria: risk of bias, consistency of effect, imprecision, indirectness, and publication bias. Working independently, two review authors made judgements about evidence quality (high, moderate, low, or very low) and resolved disagreements by discussion. We justified, documented, and incorporated into the reporting of results our judgements for each outcome.

#### RESULTS

### **Description of studies**

We have provided detailed descriptions in the Characteristics of included studies and Characteristics of excluded studies tables.

#### Results of the search

We found 26 trials reporting a perioperative intervention and included 15 of them (Adelowo 2017; Antosh 2013, Ballard 2014; Barber 2014; Billquist 2017; Bray 2017; Chan 2014; Dieter 2014; Hakvoort 2011; Henn 2016; Kamilya 2010; McClurg 2014; Pauls 2013; Thiagamoorthy 2014; Weemhoff 2010;). We excluded 11 studies from the review (Bernades 2012; Butler 2017; Crisp 2012; Frawley 2010; Glavind 2007; Gungor 2014: Jabalameli 2012; Jarvis 2005; Karp 2012; Pauls 2013; Zhu 2014). Three studies were available in abstract format only; they provided insufficient data for analysis and are awaiting assessment (Calderon 2015; Crisp 2017; Letko 2014).

#### **Included studies**

We included 15 trials in this review.

#### Setting

Trials were conducted in five countries: India (Kamilya 2010), Netherlands (Hakvoort 2011; Weemhoff 2010), United Kingdom (Bray 2017; McClurg 2014; Thiagamoorthy 2014), South Africa (Henn 2016), and the United States of America (Adelowo 2017; Antosh 2013; Ballard 2014; Barber 2014; Billquist 2017; Bray 2017; Chan 2014; Dieter 2014; Pauls 2013). All trials were published in the English language.

Length of follow-up varied from a few days postoperatively in Chan 2014 and Henn 2016 to 24 months in Barber 2014.

#### **Participants**

The 15 included trials evaluated 1992 women, all of whom received a surgical intervention for pelvic organ prolapse.

#### Interventions

Researchers reported eight different perioperative interventions.

- 2/15 trials: bowel preparation before vaginal prolapse surgery (Adelowo 2017;Ballard 2014).
- 1/15 trials: preoperative guided imagery (Billquist 2017).
- 1/15 trials: submucosal injection (infiltration) of vasoconstrictor agent at commencement of vaginal prolapse surgery (Henn 2016).
- 1/15 trials: ureteral stent (a flexible plastic hollow tube) placed in the ureter during uterosacral ligament suspension (Chan 2014).



- 1/15 trials: vaginal pack inserted after pelvic organ prolapse surgery (Thiagamoorthy 2014).
- 4/15 trials: postoperative catheter care: prophylactic antibiotics for postoperative patients requiring urinary catheterisation (Dieter 2014); an immediate postoperative trial of void (Bray 2017); timing of urinary catheter removal after a vaginal prolapse procedure (Kamilya 2010;Weemhoff 2010); and clean intermittent catheterisation for women who failed a trial of void on the first postoperative day after vaginal prolapse procedure (Hakvoort 2011).
- 1/15 trials: use of vaginal dilators postoperatively (Antosh 2013).
- 3/15 trials: pelvic floor muscle training before and after prolapse surgery (Barber 2014;McClurg 2014;Pauls 2013).

#### **Outcomes**

Included studies reported the following review outcomes.

#### **Primary outcomes**

#### **Subjective primary outcome**

- Awareness of prolapse: Barber 2014 assessed this using a variety of pelvic floor questionnaires
  - \* Pelvic Floor Distress Inventory (PFDI)
  - \* Combination of three questionnaires (with scores ranging from 0 to 100)
    - ☐ Pelvic Organ Prolapse Distress Inventory (POPDI)
    - ☐ Urinary Distress Inventory (UDI)
    - ☐ Colorectal-Anal Distress Inventory (CRADI) and/or Pelvic Organ Prolapse Symptom Score (POP-SS) - a selfcompleted seven-item questionnaire scored from 0 to 28, with higher scores indicating worse symptoms (Hagen 2009)

# **Objective primary outcomes**

- Objective failure at any site
- Vascular prolapse scored by three compartments
  - \* Anterior vaginal wall
  - \* Posterior vaginal wall
  - \* Vaginal vault or prolapse of uterus
    - ☐ The hymen is a landmark by which prolapse staging is determined: hymen or beyond anterior compartment, hymen or beyond posterior compartment, hymen or beyond apical compartment
- Any stage 2 or greater prolapse as defined by Pelvic Organ Prolapse Quantification (POPQ) (the most distal portion of the prolapse is ≤ 1 cm proximal or distal to the hymnal plane) (Barber 2014;McClurg 2014)

#### **Secondary outcomes**

# **Subjective secondary outcomes**

- Surgical field clearance, intraoperative assessment of operative field, intraoperative stooling (Adelowo 2017; Ballard 2014)
- Patient satisfaction: Global Impression of Improvement (PGI-I)

   participants were asked to choose one of seven options that represents their impression of improvement (1 = very much better, 7 = very much worse) (Antosh 2013; Barber 2014)

- Adverse events assessed immediately or up to three months post surgery
  - Vaginal atrophy (vaginal pallor, petechiae, friability, and dryness graded on a 4-point scale from none to severe) (Karp 2012a)
- Postoperative bowel function
  - \* Mean time to first bowel movement
  - \* Faecal urgency and incontinence
  - \* Pain on first bowel movement (Ballard 2014)
- Patient satisfaction related to bowel preparation (Adelowo 2017; Barber 2014)

#### Quality of life measures

- General health Short Form Health Survey (SF-12)
  - \* Form includes two questions concerning physical functioning; two questions on role limitations due to physical health problems; one question on bodily pain; one question on general health perceptions; one question on vitality (energy/fatigue); one question on social functioning; two questions on role limitations due to emotional problems; and two questions on general mental health (psychological distress and psychological well-being
  - \* Scores ≥ 50 are considered to show better than average health
  - Scores < 50 represent less than average quality of life as a result of the participant's medical condition (McClurg 2014; Pauls 2013)
- Postoperative de novo dyspareunia assessed by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) with main focus on Question 5, which represents how the participant feels about her sex life (I feel frustrated by my sex life/I feel sexually inferior because of my incontinence and/ or prolapse/I feel angry because of the impact that incontinence and/or prolapse has on my sex life)
  - Score can be between 3 and 12
    - ☐ The lower the score, the better the sex life (Antosh 2013; McClurg 2014; Pauls 2013)
- Sexual function post POP procedure
  - \* PISQ-12 Questionnaire (score range 0 to 48, with high scores indicating better overall function) (Pauls 2013; Rogers 2003)
- · Patient perioperative anxiety
  - Effects of preoperative guided imagery (GIM) for women undergoing pelvic floor reconstructive procedures on patients' anxiety, preparedness, and satisfaction (Billquist 2017)
  - \* Validated State-Trait Anxiety linventory (STAI), Pelvic Floor Distress Inventory (PFDI), and Patients' Global Impression of Improvement (PGI-I) utilised to identify differences between GIM and usual care groups

# Objective secondary outcomes

- Adverse events assessed immediately or up to three months post surgery
  - Intraoperative injury to bladder, ureter (ureteral kinking or obstruction) (Chan 2014)
  - Intraoperative or postoperative blood transfusion

    ☐ Blood loss assessed by blood loss estimation in mL,
    haemodynamic measures (Henn 2016)
  - Granulation tissue three months post vaginal surgery (granulation tissue is defined as the presence of red or pink



fleshy tissue, most often along the suture line and usually causing vaginal bleeding and vaginal discharge) (Karp 2012a)

- \* Postoperative infection, urinary tract infection (assessed by mid-stream urine culture), vaginal infection (assessed by high vaginal swab) (Antosh 2013; Bray 2017; Dieter 2014;Hakvoort 2011; Kamilya 2010; Karp 2012a; Thiagamoorthy 2014; Weemhoff 2010)
- \* Postoperative pelvic haematoma (Thiagamoorthy 2014)
- Adverse events assessed after three months post surgery

- \* Postoperative treatment for urinary incontinence
  - ☐ Conservative (pelvic floor muscle training, pessary for urinary incontinence, periurethral bulking injection, intravesical botulinum toxin injection, neuromodulation)
  - ☐ Operative (Barber 2014)
- \* Pelvic floor muscle (PFM) power or strength assessed by Brink grading system (evaluates three pelvic floor muscle contraction variables) (Brink 1994; Appendix 2

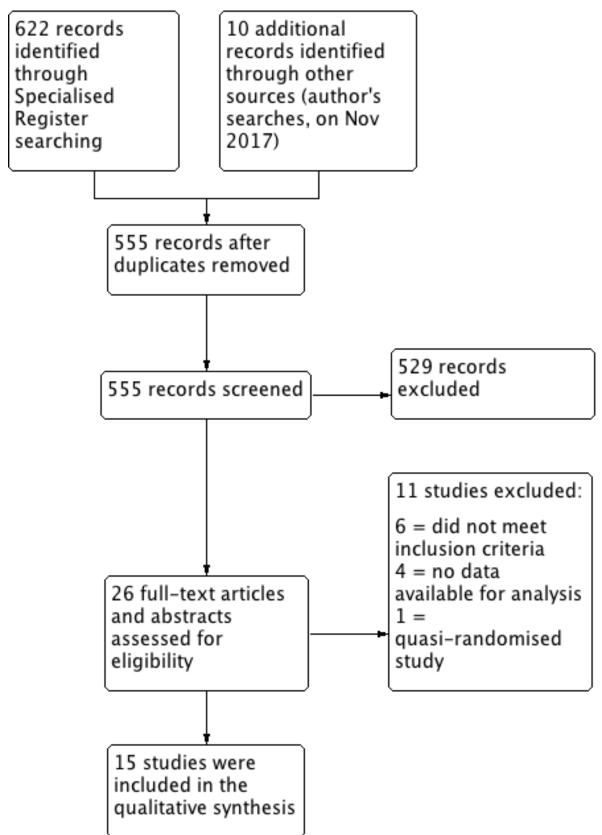
#### **Health service outcomes**

 Length of stay (days) (Adelowo 2017; Bray 2017; Crisp 2012a; Kamilya 2010; Weemhoff 2010)

We have shown the flow of literature through the assessment process in the PRISMA flowchart (Figure 1). We have given full details of the included trials in the Characteristics of included studies tables.



Figure 1. PRISMA study flow diagram.





### **Excluded studies**

We excluded 11 studies from the review (Bernades 2012; Butler 2017; Crisp 2012; Frawley 2010; Glavind 2007; Gungor 2014; Karp 2012; Jabalameli 2012; Jarvis 2005; Pauls 2013; Zhu 2014). See Characteristics of excluded studies.

### Risk of bias in included studies

We have summarised risk of bias in the included studies in Figure 2 and Figure 3.

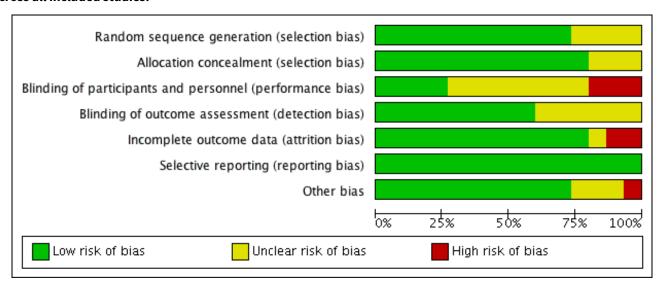


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Adelowo 2017	•	•	?	?	•	•	•
Antosh 2013 Ballard 2014	•	•		?	?	•	•
Barber 2014	•	•	<b>+</b>	•	•	•	•
Billquist 2017	•	•	?	<b>+</b>	•	•	•
Bray 2017	+	<b>+</b>	?	?	<b>+</b>	<b>+</b>	•
Chan 2014	?	?	?	?	•	•	•
Dieter 2014	?	?	• •	•	•	•	?
Hakvoort 2011	•	•	?	?	•	•	•
Henn 2016	•	•	•	?	•	•	•
Kamilya 2010	•	•	) •	•	) •	•	•
McClurg 2014	•	•	?	•	•	•	?
Pauls 2013	?	?	•	•	•	•	•
Thiagamoorthy 2014	?	•	?	•	•	•	?
Weemhoff 2010	•	•	?	•	•	•	•



Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



#### Allocation

#### Sequence generation

Eleven trials adequately described the method used to generate the randomisation sequence; we assessed these studies as having low risk of bias for this domain (Adelowo 2017; Antosh 2013; Ballard 2014; Barber 2014; Bray 2017; Hakvoort 2011; Henn 2016; Kamilya 2010; Karp 2012a; McClurg 2014, Weemhoff 2010). The remaining trials did not provide sufficient information to allow a judgement of low risk of bias; we assessed these studies as having unclear risk of bias for this domain (Chan 2014; Dieter 2014; Pauls 2013; Thiagamoorthy 2014).

#### Allocation concealment

Thirteen trials described allocation concealment by remote access or by opaque sealed envelopes (Adelowo 2017; Antosh 2013; Ballard 2014; Barber 2014; Billquist 2017; Bray 2017; Hakvoort 2011; Henn 2016; Kamilya 2010; Karp 2012a; McClurg 2014; Thiagamoorthy 2014; Weemhoff 2010). The remaining three trials did not provide sufficient information on the method used to conceal allocation to treatment groups to allow a judgement of low risk of bias; we assessed these studies as having unclear risk of bias (Chan 2014; Dieter 2014; Pauls 2013).

# Blinding

# Performance bias

We judged four trials to be at low risk of performance bias, as participants and/or researchers were blinded to treatment allocation (Ballard 2014; Dieter 2014; Henn 2016; Kamilya 2010). Six trials provided insufficient details to permit a judgement and we considered them to be at unclear risk of performance bias (Adelowo 2017; Chan 2014; Hakvoort 2011; McClurg 2014; Thiagamoorthy 2014; Weemhoff 2010). Owing to the nature of the intervention used in five trials, blinding of participants and personnel was not possible (Antosh 2013; Barber 2014; Bray 2017; Crisp 2012; Pauls 2013), and we judged these trials to be at high risk of performance bias.

#### **Detection bias**

Ten trials reported adequate blinding of outcome assessors, and we judged these studies to be at low risk of detection bias (Ballard 2014; Barber 2014; Bray 2017; Dieter 2014; Kamilya 2010; Karp 2012a; McClurg 2014; Pauls 2013; Thiagamoorthy 2014; Weemhoff 2010). Five trials provided insufficient details to enable a judgement, and we considered these trials to be at unclear risk of detection bias (Adelowo 2017; Antosh 2013; Chan 2014; Hakvoort 2011; Henn 2016). We have summarised these findings in Figure 2.

#### Incomplete outcome data

We assessed two trials as having high risk of attrition bias: Chan 2014 reported a total loss to follow-up of 36% at one month, and McClurg 2014 described 53% loss to follow-up at one year. We assessed Antosh 2013 as having unclear risk of attrition bias because study authors reported 20% loss to follow-up at six months. We judged the remaining 13 trials as being at low risk of attrition bias (Adelowo 2017; Ballard 2014; Barber 2014; Bray 2017; Crisp 2012; Dieter 2014; Hakvoort 2011; Henn 2016; Kamilya 2010; Karp 2012a; Pauls 2013; Thiagamoorthy 2014; Weemhoff 2010;).

#### **Selective reporting**

Two trials provided insufficient details to permit a judgement, and we considered these trials to be at unclear risk of reporting bias (Chan 2014; Zhu 2014a). The remaining 17 trials reported outcome data on all prespecified outcomes, and we considered them to be at low risk of reporting bias.

### Other potential sources of bias

Twelve trials provided CONSORT statements (Adelowo 2017; Antosh 2013; Barber 2014; Bray 2017; Chan 2014; Dieter 2014; Hakvoort 2011; Henn 2016; Kamilya 2010; McClurg 2014; Pauls 2013; Weemhoff 2010). We assessed one trial as being at high risk from other sources of bias, as it was published as a conference abstract with no full-text manuscript provided (Chan 2014). We assessed two trials as having unclear risk of bias for this domain: Dieter 2014 stated that subanalyses were conducted that did not change the results of the study but remain unpublished, and Thiagamoorthy



2014 did not report on three commonly expected outcomes for surgical intervention trials. We assessed the remaining 12 trials as having low risk of other potential sources of bias (Adelowo 2017; Antosh 2013; Ballard 2014; Barber 2014; Billquist 2017; Bray 2017; Hakvoort 2011; Henn 2016; Kamilya 2010; McClurg 2014; Pauls 2013; Weemhoff 2010).

#### **Effects of interventions**

See: Summary of findings for the main comparison Pelvic floor muscle training before and after prolapse surgery compared to no training in pelvic organ prolapse surgery

#### **Perioperative interventions**

#### POP surgery with or without pelvic floor training

Three trials examined the effect of pelvic floor muscle training compared to use of a control (Barber 2014; McClurg 2014; Pauls 2013). The interventions are described in Table 1.

#### **Primary outcomes**

#### **Subjective primary outcomes**

Postoperative prolapse symptoms

#### Awareness of prolapse

Barber 2014 provided no clear evidence of a difference in the number of women with awareness of prolapse at 24 months: 20.5% (31/151) in the behavioural therapy and pelvic floor muscle training (BPMT) group versus 19.5% (30/154) in the control group (odds ratio (OR) 1.07, 95% confidence interval (CI) 0.61 to 1.87; one trial, 305 women; Analysis 1.1) and reported no clear differences between the two groups in any aspect of the Pelvic Floor Distress Inventory (PFDI), including the Urinary Distress inventory (UDI), the Pelvic Organ Prolapse Distress Inventory (POPDI), and the Colorectal-Anal Distress Inventory (CRADI).

# Symptoms score

McClurg 2014 used the Validated Pelvic Organ Prolapse Questionnaire (POP-SS), in which a higher score denotes more symptoms; these researchers found no clear evidence of a difference between groups at the six-month review (mean difference (MD) 0.20, 95% CI -2.18 to 2.58; one trial, 48 women; Analysis 1.2). However, at 12 months, outcomes were better among those undergoing prolapse surgery with pelvic muscle training (mean score 2.5) than among participants in the control group (mean score 6.4) (MD -3.90, 95% CI -6.11 to -1.69; one trial, 27 women; Analysis 1.2). We judged this evidence to be of very low quality owing to the small sample size and very serious attrition.

#### **Objective primary outcome**

### Objective failure at any site

Two studies reported objective failure at any site - one at 12 months (McClurg 2014), and the other at 24 months (Barber 2014). Study results show no clear evidence of a difference between groups (OR 0.93, 95% CI 0.56 to 1.54; two trials, 327 women; moderate-quality evidence; Analysis 1.3). Barber 2014 compared rates of failure at specific sites and found no clear evidence of a difference at the hymen or beyond anterior compartment (OR 0.86, 95% CI 0.44 to 1.67; one RCT, 308 women), at the hymen or beyond posterior compartment (OR 0.63, 95% CI 0.15 to 2.70; one RCT, 308 women),

nor at the hymen or beyond apical compartment (OR 1.06, 95% CI 0.15 to 7.63; one RCT, 308 women; Analysis 1.3).

#### **Secondary outcomes**

#### **Subjective secondary outcomes**

Patient satisfaction

#### Patient Global Impression of Improvement (PGI-I)

Barber 2014 monitored this outcome at 6, 12, and 24 months postoperatively. The proportion of participants who chose one of the two top descriptions (much better or very much better) was not clearly different between treatment and control groups at any stage (6 months: OR 1.09, 95% CI 0.68 to 1.75; one trial, 336 women; Analysis 1.4; 12 months: OR 0.82, 95% CI 0.50 to 1.35; one trial, 324 women; Analysis 1.42; 24 months: OR 1.12, 95% CI 0.69 to 1.81; one trial, 304 women; Analysis 1.43).

### Sexual function post POP procedure

Two studies utilized the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Evidence was insufficient to show whether there was a difference between groups in sexual function (MD -0.78, 95% CI -4.12 to 2.56; one trial, 76 women; Analysis 1.5; McClurg 2014; Pauls 2013).

#### General health Short Form Health Survey (SF-12)

Scores were higher in the intervention group, although heterogeneity was high (MD 4.18, 95% CI 1.25 to 7.10; two trials, 74 women; I<sup>2</sup> = 78%; Analysis 1.6; McClurg 2014; Pauls 2013).

# Postoperative prolapse symptoms (International Consultation on Incontinence Questionnaire)

McClurg 2014 provided insufficient evidence to show whether there was a difference between groups for urinary symptoms (MD -0.50, 95% CI -3.22 to 2.22; one trial, 27 women; Analysis 1.7) or bowel symptoms (MD -0.80, 95% CI -3.53 to 1.93; one trial, 27 women; Analysis 1.7).

#### **Objective secondary outcomes**

Postoperative treatment for urinary incontinence

# Any repeat treatment

Barber 2014 provided insufficient evidence to show whether there was a difference between groups in the rate of retreatment for urinary incontinence (e.g. surgery, pessary, neuromodulation, periurethral bulking agents). Rates were 45% in the BPMT group (60/132) and 43% in the control group (61/141) (OR 1.09, 95% CI 0.68 to 1.76; one trial, 273 women; Analysis 1.8).

# Repeat surgery for incontinence

Barber 2014 provided insufficient evidence to show whether there was a difference between groups in the rate of reoperation for incontinence. Rates were 6% in the BMPT group (8/132) and 4% (5/141) in the control group (OR 1.75, 95% CI 0.56 to 5.51; one trial, 273 women; Analysis 1.9).

# Repeat surgery for prolapse



Evidence was insufficient to show whether there was a difference between groups in the rate of surgery or pessary use for POP. Rates were 8% (12/152) with pelvic floor exercises and 4% (7/164) with control (OR 1.92, 95% CI 0.74 to 5.02; one trial, 316 women; Analysis 1.9; Barber 2014). The rate of repeat surgery for prolapse was 3% in both groups (BMPT 4/152; control 5/164) (OR 0.86, 95% CI 0.23 to 3.26; one trial, 316 women; Analysis 1.9; Barber 2014).

### Pelvic floor muscle (PFM) power or strength

Evidence was insufficient to show whether there was a difference between the two groups in muscle strength (MD 1.10, 95% CI 0.17 to 2.03; one trial, 10 women; Analysis 1.10; McClurg 2014), repetitions (MD 2.10, 95% CI -0.75 to 4.95; one trial, 10 women; Analysis 1.10.2; McClurg 2014), or endurance (MD -0.27, 95% CI -3.12 to 2.58; one trial, 10 women; Analysis 1.10; McClurg 2014). Evidence was insufficient to show differences in pelvic floor strength, as measured by holding a muscle contraction while coughing, between the PFM group and the control group (OR 7.86, 95% CI 0.28 to 217.11; one trial, 10 participants; Analysis 1.11; McClurg 2014).

# **Health service outcomes**

#### Length of stay

Researchers provided no data for this prespecified health service outcome.

No study in this comparison reported any of our other review outcomes.

### **Preoperative interventions**

### Preoperative guided imagery vs no imagery

Billquist 2017 in a single-centre RCT investigated the impact of preoperative guided imagery (GIM) on patient anxiety and preparedness.

#### **Primary outcomes**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

Studies provided no data for subjective or objective primary outcomes of this review for this comparison.

### **Secondary outcomes**

#### **Subjective secondary outcomes**

Researchers provided no data for any of these outcomes.

#### **Quality of life measures**

Patient satisfaction was not different between the intervention group (GIM) and the control group (MD 0.50, 95% CI -0.34 to 1.34; 38 women; Analysis 2.1; Billquist 2017). Change in PFDI (Pelvic Floor Distress Inventory) scores from baseline to 6 weeks was not different between groups (MD 2.30, 95% CI -3.07 to 7.67; 38 women; Analysis 2.2; Billquist 2017).

#### **Objective secondary outcomes**

We found no data for any of these outcomes.

No study in this comparison reported any of our other review outcomes.

# Bowel preparation before vaginal prolapse surgery vs no bowel preparation

Two trials assessed the intraoperative acceptability of the surgical field and patient symptoms after preoperative bowel preparation followed by vaginal or abdominal POP surgery (Adelowo 2017; Ballard 2014).

Ballard 2014 focused mainly on vaginal POP procedures with and without mechanical bowel preparation; patients were given a clear liquid diet a day before surgery and self-administered two separate saline enemas a few hours before surgery. The control group had no bowel preparation.

Adelowo 2017 focused on abdominal laparoscopic or robotic POP procedures with mechanical bowel preparation and compared the combination of oral magnesium citrate and saline laxative sodium citrate enema versus sodium citrate enema only.

#### **Primary outcome**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

Studies provided no data for the subjective or objective primary outcomes of this review for this comparison.

#### Secondary outcomes

#### Subjective secondary outcomes

# Clearance of surgical field

Surgeons were asked to assess the surgical field in terms of accessibility, and evidence was insufficient to show whether there was a difference between groups in rates of good or excellent assessment of the surgical field by the surgeon performing vaginal (OR 0.59, 95% CI 0.21 to 1.61; 145 women; Analysis 3.1) - Ballard 2014 - or abdominal procedures at the beginning of surgery just after the first port was placed (OR 2.42, 95% CI 1.15 to 5.09; 147 women; Analysis 4.1) - Adelowo 2017 - and at the conclusion of surgery (OR 1.88, 95% CI 0.74 to 4.74; 147 women; Analysis 4.2) - Adelowo 2017. Surgeons were also asked to assess the difficulty of bowel handling during abdominal procedures, and evidence was insufficient to show whether there was a difference associated with use of oral magnesium citrate in addition to saline laxative sodium citrate enema (OR 1.10, 95% CI 0.57 to 2.10; 147 women; Analysis 4.3; Adelowo 2017).

# Postoperative bowel function

### Mean time to first bowel movement

Evidence was insufficient to show whether there was a difference between groups in mean time to first bowel movement (MD 2.60 hours, 95% CI -7.58 to 12.78; one trial, 121 women; Analysis 3.2; Ballard 2014).

#### Faecal leakage at first bowel movement

Evidence was insufficient to show whether there was a difference between groups in risk of faecal leakage at first bowel movement (OR 0.89, 95% CI 0.32 to 2.48; one trial, 121 women; Analysis 3.4; Ballard 2014).

### Faecal urgency



Evidence was insufficient to show whether there was a difference between groups in risk of faecal urgency (OR 1.11, 95% CI 0.54 to 2.26; one trial, 121 women; Analysis 3.5; Ballard 2014).

#### Pain at first bowel movement

Evidence was insufficient to show whether there was a difference between groups in risk of pain at first bowel movement (OR 0.52, 95% CI 0.21 to 1.25; one trial, 121 women; Analysis 3.6; Ballard 2014).

#### Patient satisfaction related to bowel preparation

Evidence was insufficient to show whether there was a difference between groups (OR 0.25, 95% CI 0.05 to 1.27; one trial, 143 women; Analysis 3.7; Ballard 2014). However, Adelowo 2017 found that women in the intervention group (who received a combination of oral magnesium citrate and enema) were less willing to undergo the same method of bowel preparation in the future (OR 0.17, 95% CI 0.06 to 0.48; 142 women; Analysis 4.4; Adelowo 2017), possibly owing to a higher rate of faecal incontinence in the intervention group (OR 5.70, 95% CI 2.82 to 11.53; 149 women; Analysis 4.5; Adelowo 2017).

#### **Objective secondary outcomes**

Trials provided no data for any of the objective secondary outcomes.

#### **Health service outcomes**

Length of stay

In Adelowo 2017, most women stayed for one night and data show no clear evidence of a difference between groups (OR 1.89, 95% CI 0.34 to 10.65; 148 women; Analysis 4.6; Adelowo 2017).

No study in this comparison reported any of our other review outcomes.

#### Intraoperative interventions

Submucosal injection of vasoconstrictor agent vs saline at commencement of vaginal prolapse surgery

#### **Primary outcomes**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

We found no data for subjective or objective primary outcomes of this review for this comparison.

#### **Secondary outcomes**

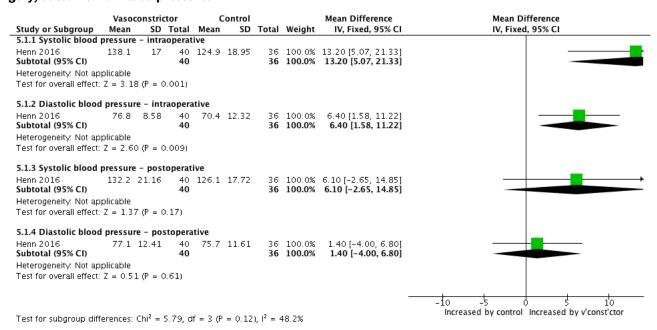
**Subjective secondary outcomes** 

Adverse events

#### Increased blood pressure

Use of a vasoconstrictor may increase mean intraoperative systolic blood pressure (MD 13.20 mmHg, 95% CI 5.07 to 21.33; one trial, 76 women) and diastolic blood pressure (MD 6.40 mmHg, 95% CI 1.58 to 11.22; one trial, 76 women) compared with placebo (normal saline). Evidence was insufficient to show whether there was a difference between groups in mean postoperative systolic blood pressure (MD 6.10 mmHg, 95% CI -2.65 to 14.85; one trial, 76 women) or diastolic blood pressure (MD 1.40 mmHg, 95% CI -4.00 to 6.80; one trial, 76 women). See Analysis 5.1 and Figure 4.

Figure 4. Forest plot of comparison: 2 Infiltration of vasoconstrictor agent at commencement of vaginal prolapse surgery, outcome: 2.2 Blood pressure.



Increased heart rate

Evidence was insufficient to show whether there was a difference between groups in intraoperative heart rate (MD -3.30 beats per



minute, 95% CI -10.90 to 4.30; one trial, 76 women) or postoperative heart rate (MD -2.50 beats per minute, 95% CI -8.55 to 3.55; one trial, 76 women; Analysis 5.2; Henn 2016).

#### **Objective secondary outcomes**

Adverse events

#### **Blood loss**

Maximal blood loss was 328 mL in the placebo group and 208 mL in the intervention group. None of the participants were reported to receive intraoperative or postoperative blood transfusion. Use of a vasoconstrictor reduced mean intraoperative blood loss compared with placebo (normal saline) (MD -29.60 mL, 95% CI -56.57 to -2.63; one trial, 76 women; Analysis 5.3; Henn 2016). The mean difference in blood loss between groups was 30 mL.

No study reported any of our other prespecified objective outcomes.

#### **Health service outcomes**

Length of stay

We found no data for this outcome.

No study in this comparison reported any of our other review outcomes.

# Intraoperative ureteral stent placement before uterosacral ligament suspension vs no stent

In a single trial, Chan 2014 randomised 93 women with stage II to IV pelvic floor prolapse who were undergoing uterosacral ligament suspension with and without ureteric stents.

#### **Primary outcomes**

# **Objective primary outcome**

Awareness of prolapse; objective failure at any site

Trials provided no data for the subjective or objective primary outcomes of this review for this comparison.

# Secondary outcomes

#### **Subjective secondary outcomes**

We found no data for any of our prespecified subjective outcomes.

# **Objective secondary outcomes**

Adverse events assessed immediately or up to 3 months post surgery

# Intraoperative ureteral injury

Evidence was insufficient to show whether there was a difference in the rate of ureteral injury (ureteral kinking or obstruction) between surgical procedures without (8.7%; 4/46) or with (6.7%; 3/45) ureteric stent insertion (OR 0.75, 95% CI 0.16 to 3.56; one trial, 91 women; Analysis 6.1).

#### **Health service outcomes**

Length of stay

We found no data for this outcome.

No study in this comparison reported any of our other review outcomes.

#### **Postoperative interventions**

# Vaginal pack insertion vs no pack after pelvic organ prolapse surgery

Thiagamoorthy 2014 assessed the effect of vaginal packing compared with no vaginal packing following pelvic floor surgery in 173 women; a 7.5-metre length of 10-cm-wide cotton gauze roll soaked in proflavine antiseptic solution was packed tightly into the vaginal vault of women with vaginal packing following surgery. The study design allowed surgeons to use a vaginal pack in the control group, and 6% (5/87) of this group had a pack inserted. Three patients in the control group had complications related to bleeding (one returned to the operating theatre for vaginal bleeding, and two were readmitted owing to infected pelvic haematoma) as compared with none in the pack group.

#### **Primary outcomes**

### **Primary objective outcome**

Awareness of prolapse; objective failure at any site

Trials provided no data for the subjective or objective primary outcomes of this review for this comparison.

#### **Secondary outcomes**

#### **Subjective secondary outcome**

Postoperative pain

Thiagamoorthy 2014 reported data on postoperative pain based on the short form McGill Pain Scale. This trial provided no evidence of a difference in pain scores between the vaginal pack group as compared with the control group. Data were reported as medians with interquartile ranges and therefore were not suitable for meta-analysis.

#### **Objective secondary outcomes**

Major healing abnormalities post vaginal surgery

#### Postoperative pelvic haematoma

A total of 51 women (59%) from the vaginal packing group and 56 (64%) from the control group underwent a vaginal hysterectomy followed by transvaginal ultrasound six weeks after the operation (haematomas with mean dimensions > 2 cm³ were regarded as significant). Evidence was insufficient to show whether there was a difference between groups in the rate of pelvic haematoma: 7% (4/55) in the vaginal pack group versus 15% (9/61) in the control group (OR 0.45, 95% CI 0.13 to 1.57; one trial, 116 women; Analysis 7.1; Thiagamoorthy 2014).

#### Postoperative infection: urinary tract or vaginal infection

#### **Urinary tract infection**

Evidence was insufficient to show whether there was a difference between groups at one day postoperative follow-up (OR 0.85, 95% CI 0.31 to 2.33; one trial, 170 women) or at six weeks postoperative follow-up (OR 1.05, 95% CI 0.50 to 2.18; one trial, 169 women; Analysis 7.2; Thiagamoorthy 2014).



#### Vaginal infection

Evidence was insufficient to show whether there was a difference between groups at one day postoperative follow-up (OR 0.79, 95% CI 0.31 to 2.01; one trial, 171 women) or at six weeks postoperative follow-up (OR 0.59, 95% CI 0.31 to 1.14; one trial, 169 women; Analysis 7.3; Thiagamoorthy 2014).

#### **Health service outcomes**

#### Length of stay

Trials provided no data for this outcome.

No study in this comparison reported any of our other review outcomes.

# Prophylactic antibiotics for postoperative patients requiring urinary catheterisation vs no antibiotics

Dieter 2014 included women who underwent POP surgery or midurethral sling or both and failed postoperative trial of void (TOV), in which the bladder was backfilled with 300 mL of saline, the indwelling catheter (IDC) was removed, and participants asked for an immediate void. Post void residual was measured by catheterisation or by bladder scan. Participants passed TOV if residual volume measured less than 100 mL or voided more than 50% of the prevoid volume (> 200 mL). Participants who failed TOV were discharged with IDC or with intermittent self-catheterisation (ISC) as per their preference.

#### **Primary outcomes**

#### **Objective primary outcome**

7.1 Awareness of prolapse; objective failure at any site

We found no data for the subjective or objective primary outcomes of this review for this comparison.

#### **Secondary outcomes**

#### **Subjective secondary outcomes**

Researchers provided no data for any of our prespecified subjective secondary outcomes.

#### **Objective secondary outcomes**

Postoperative infection: urinary tract or vaginal infection

#### **Urinary tract infection**

Evidence was insufficient to show whether there was a difference between women who received prophylactic antibiotics (nitrofurantoin 100 mg once daily) and women given control in the risk of developing a urinary tract infection (UTI) postoperatively (OR 1.94, 95% CI 0.83 to 4.53; one trial, 159 women; Analysis 8.1; Dieter 2014). In total, 93% (75/81) of women in the placebo group and 90% (70/78) of those in the antibiotic group were discharged with an indwelling catheter, and 5% (4/81) in the placebo group and 9% (7/78) in the antibiotic group were discharged using intermittent self-catheterisation.

#### **Health service outcomes**

#### Length of stay

Trials provided no data for this outcome.

No study in this comparison reported any of our other review outcomes.

# An immediate trial of void (no catheter) after prolapse surgery performed via the vaginal route vs suprapubic catheterisation

One trial compared an immediate trial of void after prolapse surgery performed via the vaginal route versus suprapubic catheterisation (Bray 2017). One group had immediate catheter removal as soon as the surgery was completed. Patients were encouraged to void as soon as they felt the urge. At eight hours postoperatively, if they had not passed urine, in/out catheterisation was performed, and it was repeated every eight hours or sooner if the patient felt uncomfortable or unable to void. The second group had a percutaneous suprapubic catheter (Bonanno SPC) placed intraoperatively. This was on free drainage until day 2 postoperatively, when it was clamped and patients were encouraged to void spontaneously. Patients passed the post void test if urine residual was less than 100 mL; otherwise the SPC was left unclamped overnight and the patient renewed TOV.

#### **Primary outcome**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

Trials provided no data for the subjective or objective primary outcomes of this review for this comparison.

#### **Secondary outcomes**

#### **Subjective secondary outcomes**

We found no data for any of our prespecified subjective secondary outcomes.

#### **Objective secondary outcomes**

#### **Urinary tract infection**

Bray 2017 reported the prevalence of UTI after postvaginal prolapse surgery; these researchers found a lower rate of UTI in women who had an immediate trial of void versus those who had suprapubic catheterisation (OR 0.18, 95% CI 0.05 to 0.60; one trial, 60 women; Analysis 9.1).

# **Health service outcomes**

# Length of stay

Trial results show no clear differences between groups (OR 0.65, 95% CI 0.20 to 2.05; 60 women; Analysis 9.2; Bray 2017).

No study in this comparison reported any of our other review outcomes.

# Clean intermittent catheter vs indwelling catheter for women who fail trial of void on the first postoperative day after vaginal prolapse procedure

#### **Primary outcome**

# **Objective primary outcome**

Awareness of prolapse; objective failure at any site

We found no data on the subjective or objective primary outcomes of this review for this comparison.



#### Secondary outcomes

#### Subjective secondary outcome

#### Patient satisfaction

Researchers evaluated patient satisfaction by asking participants whether they would choose the same treatment again and noted no clear differences between groups (OR 1.26, 95% CI 0.44 to 3.65; 87 women; Analysis 10.3; Hakvoort 2011).

#### **Objective secondary outcome**

### Postoperative infection, urinary tract

The clean intermittent catheter group had lower levels of bacteriuria (OR 0.24, 95% CI 0.08 to 0.69; one trial, 78 women; Analysis 10.1) and urinary tract infection (OR 0.19, 95% CI 0.06 to 0.62; one trial, 87 women; Analysis 10.2; Hakvoort 2011).

Hakvoort 2011 also reported on duration of hospitalisation and/or catheterisation, but data were not in a form that could be entered into analyses.

No study in this comparison reported any of our other review outcomes.

# Indwelling catheter removal following vaginal prolapse procedure postoperative day (POD) 1 vs POD 4

Kamilya 2010 compared the timing for removal of an indwelling catheter following a vaginal prolapse procedure. Women in the intervention group had an indwelling catheter for one day, whereas those in the control group had a catheter for four days. Researchers selected the study population and excluded women who had undergone bladder suspension or vaginal mesh repair and those with long-standing prolapse. Patients who had their catheter removed on the first postoperative day and failed trial of void had recatheterisation for three additional days.

# **Primary outcome**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

We found no data for the subjective or objective primary outcomes of this review for this comparison.

# **Secondary outcomes**

## **Objective secondary outcome**

Postoperative infection, urinary tract

The group with an indwelling catheter for one day had a lower rate of UTI than the group that had a catheter for four days (OR 0.10, 95% CI 0.04 to 0.28; one trial, 197 women; Analysis 11.1; Kamilya 2010).

#### **Subjective secondary outcome**

Studies provided no data for any prespecified subjective outcomes.

#### **Health service outcomes**

# Length of hospital stay

Hospital stay was significantly shorter in the one-day group (MD -1.18, 95% CI -1.44 to -0.92; 197 women; Analysis 11.3; Kamilya 2010), although recatheterisation that may increase hospital stay

was higher among patients who had the catheter removed on POD 1 than among those who had a catheter for four days (OR 3.10, 95% CI 1.30 to 7.40; 197 women; Analysis 12.3; Kamilya 2010).

No study in this comparison reported any of our other review outcomes.

# Indwelling catheter removal following anterior vaginal wall repair POD 2 vs POD 5

Weemhoff 2010 compared different protocols of timing for removal of an indwelling catheter following anterior vaginal wall repair (anterior colporrhaphy with or without concomitant prolapse or continence procedure). In this multi-centre RCT, researchers compared the incidence of UTI and recatheterisation and length of hospital stay. Patients who failed TOV (post void urine residual > 200 mL) had a catheter inserted for another 24 hours. After 24 hours, the catheter was removed and the patient had another TOV.

#### **Primary outcome**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

Studies provided no data for the subjective or objective primary outcomes of this review for this comparison.

#### Secondary outcomes

#### Subjective secondary outcomes

We found no data for any of our prespecified subjective secondary outcomes.

#### **Objective secondary outcomes**

# Postoperative infection: urinary tract

Urine culture was taken as the catheter was removed for the first time, and women in the POD 2 group were less likely to have a UTI (OR 0.48, 95% CI 0.25 to 0.90; one trial, 250 women; Analysis 12.1; Weemhoff 2010). Repetition of temporary catheterisation increases the risk for UTI. Patients were more likely to be recatheterised if they had the catheter removed after two days (OR 4.01, 95% CI 1.93 to 8.35; 250 women; Analysis 12.2; Weemhoff 2010). The most desired result would be a low rate of UTI combined with a high proportion of women passing their first trial of void. Study authors compared the proportions of women in each group who had both desired outcomes and found no clear evidence of a difference (OR 1.05, 95% CI 0.62 to 1.78; one trial, 250 women; Analysis 12.3; Weemhoff 2010).

#### **Health service outcomes**

# Length of stay

Researchers reported data as medians, and these values were not suitable for analysis.

### Use vs no use of vaginal dilators postoperatively

POP surgery can negatively affect sexual function by reducing vaginal calibre and length and producing scarring that may lead to de novo dyspareunia. Antosh 2013 assessed the impact of daily postoperative use of vaginal dilators on rates of de novo dyspareunia following a native tissue posterior repair. The control group was given the same surgical intervention without dilators. Researchers performed perineorrhaphy with posterior



colporrhaphy in 83% of participants in the dilator group and in 87% of those in the control group. They estimated subjective outcomes by using the PISQ. They also assessed postoperative adverse events.

#### **Primary outcome**

#### **Objective primary outcome**

Awareness of prolapse; objective failure at any site

Trials provided no data for the subjective or objective primary outcomes of this review for this comparison.

#### **Secondary outcomes**

#### Subjective secondary outcome

#### Patient satisfaction

Data provide no clear evidence of a difference between groups in PGI-I scores at six months (MD -0.30, 95% CI -0.63 to 0.03; one trial, 52 women; Analysis 13.3; Antosh 2013).

#### **Objective secondary outcome**

We found no data for any of our prespecified health service outcomes.

#### **Quality of life measures**

#### Sexual function post POP procedure

Six months post operation, data show no clear evidence of a difference between groups in PISQ scores (MD -0.20, 95% CI -2.92 to 2.52; one trial, 50 women; Analysis 13.5; Antosh 2013).

PISQ Question 5 was given a special scope: this question represents how the patient feels about her sex life. Upon six-month review, patient responses provided no clear evidence of a difference between groups, with mean values of 2.8 and 3.1 for dilator and control groups, respectively (MD -0.30, 95% CI -0.89 to 0.29; one trial, 50 women; Analysis 13.6; Antosh 2013).

# Postoperative de novo dyspareunia

We found no conclusive evidence to show that the rate of de novo dyspareunia at 6 months differed between groups: intervention group 3.8% (1/26) versus control group 12.5% (3/24) (OR 3.57, 95% CI 0.35 to 36.94; one trial, 50 women; Analysis 13.7; Antosh 2013).

# **Objective secondary outcomes**

# Major healing abnormalities post vaginal surgery

Concern might arise that pressure produced when the vaginal dilator was introduced could interfere with vaginal healing; in the case of mesh utilisation, a higher rate of mesh exposure may occur. Studies report that mesh was utilised during sacral colpopexy or anterior repair and exposure was seen in 3.3% (1/30) in the dilator group and in no participants in the control group, for a difference that did not reach statistical significance (OR 3.10, 95% CI 0.12 to 79.23; one trial, 60 women; Analysis 13.1; Antosh 2013).

#### Vaginal atrophy

No data for this outcome were measured on a 4-point scale, but at six months, no clear evidence shows a difference between groups in

vaginal calibre (measured by a ring pessary) (MD -0.20, 95% CI -0.93 to 0.53; one trial, 49 women; Analysis 13.4; Antosh 2013).

Postoperative infection: urinary tract or vaginal infection

#### **Urinary tract infection**

In the dilator group, 23% (7/30) of women had a urinary tract infection versus 7% (2/30) in the control group. This difference was not statistically significant (OR 4.26, 95% CI 0.81 to 22.53; one trial, 60 women; Analysis 13.2; Antosh 2013).

#### **Health service outcomes**

Length of hospital stay

Studies provided no data for this outcome.

No study in this comparison reported any of our other review outcomes.

#### Other analyses

Studies available for any comparison were insufficient for us to carry out planned subgroup and sensitivity analyses.

#### DISCUSSION

# **Summary of main results**

Perioperative interventions may be time-consuming for patients and healthcare providers. Patients might be required to attend more hospital visits and sometimes experience unnecessary burdens. In an era of limited time and economic resources, there is a constant onus to demonstrate efficacy and safety for each intervention. A broad spectrum of interventions are being undertaken in an attempt to improve outcomes for patients who undergo prolapse surgery. Each intervention is associated with some patient burden or a related risk. This review generally demonstrates lack of data on perioperative interventions at prolapse surgery. Primary outcomes refer to only two or three trials and are not relevant to most other trials, for which important outcomes were reported in a pragmatic fashion.

A structured programme of pelvic floor muscle training before and after prolapse surgery was not associated with any clear benefit. Perioperative pelvic floor muscle training (PFMT) is utilised to improve postoperative prolapse and bladder outcomes. Bladder dysfunction is seen in 73% of women who undergo prolapse surgery. Postoperatively, bladder function may improve, worsen, or remain unchanged (Ellerkmann 2001). Three studies assessed pelvic organ prolapse (POP) surgery with or without pelvic floor training and demonstrated no advantage, except for very lowquality evidence of an improved outcome in a single trial that used a validated pelvic floor questionnaire for those undergoing PFMT. One large trial evaluated reintervention or reoperation for prolapse or incontinence and found no clear evidence of a difference between groups at 24 months. Findings from this limited meta-analysis are consistent with clinical practice, where intense perioperative PFMT is not the norm. These extra interventions place a greater cost burden on patients and communities without measurable benefit and cannot be endorsed in routine practice.

Most of the remaining interventions were evaluated in single trials only. Trial results show a small but not clinically significant reduced



blood loss of 30 mL after vaginal infiltration with vasoconstrictor as compared to surgery without vasoconstrictor. Preoperative bowel preparation or use of intraoperative ureteric stents provided no tangible benefits. Both postoperative vaginal packing and postoperative use of vaginal dilators require further evaluation, as the sample size of trials was limited.

The theoretical benefits of bowel preparation include improved surgical field vision achieved by eliminating bulky intraluminal contents and reduced risk of contamination if the bowel should be opened inadvertently. Adelowo 2017 and Ballard 2014 demonstrated no advantages associated with preoperative bowel preparation versus no bowel preparation for those undergoing vaginal prolapse surgery. Preoperative bowel preparation before vaginal prolapse surgery appears to offer little advantage while placing a significant burden on the patient.

POP surgery requires dissection that can be associated with substantial blood loss. Hydrodissecton is utilised in most vaginal prolapse repairs to aid dissection and to minimise blood loss (Lensen 2011). A single study compared submucosal vaginal injection with ornipressin or saline. Henn 2016 found a clinically insignificant reduction in blood loss (30 mL) in the vasoconstrictor group when compared to the control group. However, higher blood pressure was recorded during the procedure in the intervention group. Although differences in blood loss may not be clinically significant and blood transfusion is only rarely required, limited intraoperative bleeding may contribute to better visualisation of the surgical field and improved tissue handling.

Vaginal packing following vaginal prolapse repair is commonly undertaken routinely in an attempt to reduce adverse effects such as bleeding and pelvic haematoma. Thiagamoorthy 2014 demonstrated no significant difference in postoperative pain and a non-significantly lower rate of pelvic haematoma diagnosed by ultrasound assessment at six weeks. Pelvic haematoma was diagnosed in 7% of the pack group as compared to 15% of the control group. Although this study is not conclusive, having a postoperative vaginal pack seems to lead to little or no morbidity and potential benefit for patients in reduced pelvic haematoma and postoperative bleeding that may have been realised with a larger sample size. Further evaluation of this intervention is required.

Urinary retention is one of the best known early postoperative complications in women undergoing POP procedures; it may lead to urinary tract infection and urinary voiding dysfunction in cases of bladder overdistension. Surgeons frequently employ prophylactic antibiotics to minimise the risk of urinary tract infection; however the benefit of this approach remains to be proved in a doubleblind randomised controlled trial. Dieter 2014 failed to prove the superiority of prophylactic antibiotics over the control intervention in preventing the need for urinary tract infection treatment. Bray 2017 compared suprapubic catheterisation versus immediate trial of void for women undergoing prolapse surgery via the vaginal route and found a significantly reduced rate of postoperative urinary tract infection in the immediate trial of void group; however generalisability of these trial results is limited, as use of a vaginal pack and combined continence surgery were exclusions for this trial. Hakvoort 2011 compared clean intermittent catheterisation versus an indwelling catheter inserted for three days among women who failed trial of void on the first postoperative day (> 150 mL after the first void) and reported that the clean intermittent catheter group had significantly lower rates of bacteriuria and

urinary tract infection. Researchers described significant variation in the duration of catheterisation. Kamilya 2010 showed that removal of an indwelling catheter on postoperative day (POD) 1 is associated with higher rates of failed trial of void and need for repeat catheterisation; however four days of catheterisation was associated with higher risk for urinary tract infection and prolonged hospital stay.

Weber 2000 reported a rate of 11% for de novo dyspareunia following POP surgery, and Antosh 2013 was unable to demonstrate a beneficial reduction in dyspareunia, among those who used vaginal dilators at six months (4%) as compared to those who did not (12%).

# Overall completeness and applicability of evidence

We found a significant paucity of trials evaluating perioperative interventions at the time of prolapse surgery. Three trials were available to assess the role of PFMT, and only single trials were available for the remaining interventions.

# Quality of the evidence

The quality of the evidence ranged from very low to moderate. The main limitation was imprecision, associated with small sample sizes and low event rates.

The quality of the reporting was generally good, with description of the randomisation process and inclusion of flow diagrams, allocation concealment, and methods of blinding of participants and reviewers reported. Most recent trials utilised validated pelvic questionnaires; however studies show significant variation in the questionnaires used, which limits the potential for meta-analysis. Finally, trials should ensure the clinical applicability of the interventions and outcomes assessed.

### Potential biases in the review process

No review authors have any conflict of interest to report, and the review authors are not aware of any potential biases in the review process.

# Agreements and disagreements with other studies or

Although we were not able to identify significant advantages of perioperative pelvic floor muscle training (PFMT) at the time of prolapse surgery, this finding is similar to that of the Frawley 2010 randomised controlled trial, which found no difference between those undergoing hysterectomy and/or prolapse surgery with or without PFMT when assessed by blinded reviewers at 12 months. However in an RCT with follow-up by blinded reviewers at three months, Jarvis 2005 reported improved urinary symptoms, quality of life, and urinary diary outcomes among those undergoing incontinence and/or prolapse surgery with perioperative PFMT as apposed to those without. Patients scheduled for urinary incontinence surgery and/or prolapse surgery were included, and the article does not state how many women underwent treatment for urinary incontinence only. Therefore a possible selective bias may have had an impact on study outcomes.

This review demonstrated no advantage of utilising preoperative bowel preparation for those undergoing vaginal prolapse surgery, and Cochrane systematic reviews evaluating the benefits of preoperative bowel preparation for women undergoing an elective



colorectal surgery Güenaga 2011 or operative gynaecological surgery - Muzil 2003 - have reported similar findings.

### **AUTHORS' CONCLUSIONS**

#### Implications for practice

Review authors found a paucity of data about perioperative interventions in pelvic organ prolapse surgery. Two small studies found that a structured programme of pelvic floor muscle training (PFMT) before and after prolapse surgery did not consistently demonstrate any benefit for the intervention. With regard to other interventions (preoperative bowel preparation and injection of vasoconstrictor agent, ureteral stent placement during uterosacral ligament suspension, postoperative vaginal pack insertion, use of vaginal dilators, prophylactic antibiotics for postoperative catheter care), studies have provided no evidence regarding rates of recurrent prolapse and no clear evidence that they were associated with clinically meaningful reductions in adverse effects such as intraoperative or postoperative blood transfusion, intraoperative ureteral injury, or postoperative urinary tract infection.

#### Implications for research

Significant further research is required in all areas of perioperative interventions. In particular, trialists should report objective failure at any site, subjective postoperative prolapse symptoms, and adverse effects including intraoperative blood loss and blood transfusion, intraoperative ureteral injury, and postoperative urinary tract infection.

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### CHARACTERISTICS OF STUDIES

# **Characteristics of included studies** [ordered by study ID]

# Adelowo 2017

Methods	Trial design: single-centre, single-blind randomised controlled trial				
Participants	153 enrolled				
	Number of women randomised: 153 (74 intervention group, 79 control group)				
	Number of women analysed: 148 (71 intervention group, 77 control group)				
	Mean age: 48.5 (47.6 to 49.3) years in intervention group, 48.7 (47.7 to 49.5) years in control group				
	Inclusion criteria: women > 18 years of age, stage II or greater apical prolapse, scheduled to undergo laparoscopic or robotic reconstructive prolapse surgery				
	Exclusion criteria: not able to provide informed consent in English; current pregnancy; plans for future pregnancy; history of uterine, cervical, or vaginal cancer; abdominopelvic irradiation; known adverse reactions to synthetic materials; colorectal cancer; contraindication to laparoscopy or use of magnesium citrate				
	Setting: female pelvic medicine and reconstructive surgery clinic at Mount Auburn Hospital, Cambridge, MA, USA				
	Timing: January 2012 to September 2015				
Interventions	Intervention: mechanical bowel preparation with 10-ounce bottle of oral magnesium citrate saline laxative 1 day before surgery with 133 mL sodium citrate enema the night before and the morning of surgery				
	Control: mechanical bowel preparation with sodium phosphate enema alone				
	Both intervention (mechanical bowel preparation) and control: 133 mL sodium phosphate enema the night before and the morning of minimally invasive pelvic reconstructive surgery with or without a con comitant vaginal reconstructive or continence procedure				
	Clear liquid diet the day before surgery, nothing to eat or drink from midnight				
Outcomes	<b>Primary outcomes:</b> intraoperative quality of the surgical field measured by a modified version of the self-administered questionnaire (Yang 2011) completed by the surgeon immediately after the procedure; evaluation of the surgical field as excellent, good, fair, or poor at 2 time points (after laparoscopic port placement and at the end of the procedure)				
	<b>Secondary outcomes:</b> surgeons' assessment of bowel handling, bowel preparation, bowel handling and visualisation (assessed as excellent, good, fair, or poor), and .				
	bowel symptoms (patient-reported tolerability symptoms in the preop area, assessed by question- naires regarding bowel and quality of life symptoms (abdominal pain, nausea, and embarrassment rat- ed on a 10-point severity scale from none to worst possible))				

<sup>\*</sup> Indicates the major publication for the study



# Adelowo 2017 (Continued)

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated block randomisations
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes (by one of the investigators who was not involved in data collection or assessment of any outcomes)
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Participants could not be blinded to the intervention. Patients were advised not to discuss the assigned bowel preparation with the medical team
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Patients were not blinded to the intervention, which might influence the secondary outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	148/153 (97%) completed the study
Selective reporting (reporting bias)	Low risk	None
Other bias	Low risk	Appears free of other biases

# Antosh 2013

Methods	Trial design: single-centre, parallel randomised controlled trial
Participants	Number randomised: 60 women (30 to vaginal dilator group, 30 to control group)
·	Number analysed: data available on 51 women at 3-month follow up and on 52 women at 6-month follow-up
	Mean age: 53.9 years (SD 9.6) in dilator group, 51.8 years (SD 11.0) in control group
	Inclusion criteria: at least 18 years of age, English speaking, sexually active in the past 6 months with heterosexual vaginal intercourse, available for 6-month follow-up, able to complete study question-naires and use vaginal dilators
	Exclusion criteria: significant baseline dyspareunia (determined by response "usually" or "always" to Question 5: "Do you feel pain with sexual intercourse" on the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12); pregnancy; prior pelvic radiation therapy; active vaginal infection or herpes; posterior colporrhaphy not performed at the time of surgery; postoperative wound complication such as rectovaginal haematoma, mesh erosion, or vaginal wound infection at the 2-week postoperative randomisation visit
	Location: Washington, DC, USA
	Timing: November 2010 to February 2012
Interventions	All participants underwent posterior colporrhaphy via the standard technique or site specific or a combination of both, with a midline posterior vaginal wall incision, +/- concomitant surgery - perineorrhaphy, other prolapse/continence procedures (hysterectomy, apical suspension, AC, sling) as required



#### Antosh 2013 (Continued)

Intervention: vaginal dilator group (n = 30). At the 2-week postoperative visit, participants randomised to this group were provided with an extra-small vaginal dilator and printed instructions for vaginal softening exercises, which involved massaging the posterior wall of the vagina gently with the dilator and using lubricating jelly for 5 to 10 minutes daily, commencing 4 to 8 weeks postoperatively. Participants in this group were also provided with a 7-day diary before the 8-week and 3-month follow up visits for assessment of compliance with dilator use

Comparison: control group (n = 30): participants in this group were randomised at the 2-week postoperative visit to no dilator use

All participants underwent a pelvic organ prolapse quantification (POPQ) examination and a vaginal calibre measurement at baseline, 3 months, and 6 months postoperatively

#### Outcomes

**Primary outcome:** de novo postoperative dyspareunia defined as the response "usually" or "always" on the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12 Question 5 ("Do you feel pain with sexual intercourse?") from a woman who answered "never", "seldom", or "sometimes" on the baseline questionnaire.

**Secondary outcomes:** change in sexual function (using the overall Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12 score before and after surgery), patient satisfaction (using Patient Global Impression of Improvement scores), effect of vaginal calibre, POPQ measurements of sexual function after surgery

#### Notes

Funding: American Congress of Obstetricians and Gynecologists, Boehringer Ingelheim Pharmaceuticals Inc, Research Award in Female Sexual Dysfunction

One study author is a consultant for several pharmaceutical and medical technology companies. The other study authors did not report any potential conflicts of interest.

#### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera-	Low risk	Randomisation occurred at the 2-week postoperative visit.
tion (selection bias)		Quote: "patients were randomized to vaginal dilators or no vaginal dilators by the statistician using a computer generated randomisation schedule"
Allocation concealment (selection bias)	Low risk	Quote: "Group assignments were sealed in consecutively numbered, sealed, opaque envelopes"
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Because of the nature of the study, it was not possible to blind patients or surgeons to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Patients and surgeons were not blinded, but validated questionnaires were utilised to assess subjective outcomes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Results show 13% loss to follow-up based on the 6-month visit - 25/30 women in the vaginal dilator group and 27/30 women with no vaginal dilators (control) attended the 6-month visit.
		22/30 women in the vaginal dilator group and 26/30 women in the control group completed both the 3-month questionnaire and the 6-month follow-up visit.



Antosh 2013 (Continued)		8 women in the vaginal dilator group and 4 women in the control group are missing follow-up data at the 3-month or 6-month time point, which equates to 20% incomplete data.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported.
Other bias	Low risk	Appears free of other biases

# Ballard 2014

Methods	Trial design: single-centre, parallel-arm randomised controlled trial		
Participants	Number of women randomised: 150 (75 per group)		
	Number of women analysed: 145 (72 intervention group, 73 control group)		
	Mean age: 62 years (SD 10) in intervention group, 60 years (SD 10) in control group		
	Inclusion criteria: women > 19 years of age, scheduled to undergo reconstructive vaginal prolapse surgery to include an apical suspension with posterior compartment repair		
	Exclusion criteria: colorectal cancer, inflammatory bowel disease, history of bowel resection, neurological disorder, undergoing chemotherapy or radiation, constipation according to Rome III guidelines pregnancy		
	Setting: Urogynecology Care Clinic at the University of Alabama, Birmingham, Alabama, USA		
	Timing: January 2011 to August 2012		
Interventions	Intervention: vaginal surgery with bowel preparation (intake of a clear liquid diet, self-administration of 2 separate saline enemas at 4 pm and 6 pm the afternoon before the day of surgery, along with nil be mouth after midnight on the day of surgery)		
	Comparison: vaginal surgery without bowel preparation (continuation of regular diet and nil by mouth after midnight on the day of surgery)		
	Both groups were given written instructions on a high-fibre diet (20 to 25 g/d) as a guideline to follow postoperatively		
Outcomes	<b>Primary outcome:</b> surgeon acceptability, measured by a self-administered questionnaire completed by the primary surgeon to assess the intraoperative surgical field		
	<b>Secondary outcomes:</b> patients' overall satisfaction (assessed by a self-administered questionnaire consisting of modified patient satisfaction question), severity of perioperative bowel symptoms (including time to first bowel movement, pain, urgency, and faecal leakage)		
Notes	Intention-to-treat analysis: yes		
	Sample size calculation: sample size of 70 in each group, calculated to provide 80% power to detect a 20% difference in rates of acceptable bowel preparation between groups, with 2-sided significance of 5%. Seventy-five participants were recruited to each group to allow for an assumed 7% attrition rate.		
	Trial registration: ClinicalTrials.gov NCT01431040		
	Funding: in part by the UAB Centre for Clinical and Translational Science, grant number UL1TR00165 from the National Centre for Advancing Translational Sciences (NCATS) and National Centre for Research Resources (NCRR) component of the National Institutes of Health (NIH). Also partially funded by 2K24-SDK068389 to Holly E Richter from the National Institute of Diabetes and Digestive and Kidney		



#### Ballard 2014 (Continued)

Disease (NIH). Dr Richter is a consultant for several pharmaceutical and medical technology companies. The other study authors reported no potential conflicts of interest.

Risk	_∧f	hiac

Bias Authors' judgement Support for judgement		Support for judgement	
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence	
Allocation concealment (selection bias)	Low risk	Quote: "sequentially numbered, opaque, sealed and stapled envelopes"	
Blinding of participants and personnel (perfor- mance bias) All outcomes	Low risk	Participants were not blinded owing to the nature of the intervention. Surgical personnel were blinded to group allocation.	
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analysts were blinded to group allocation.	
Incomplete outcome data (attrition bias) All outcomes	Low risk	75 women were randomised to each group. 72 in the intervention group received allocated treatment (1 withdrew and 2 had surgery cancelled), and 73 in the control group received allocated treatment (2 withdrew from the study) Secondary analysis was conducted on the 121 women who completed bowel diaries: a 7-day diary immediately before surgery and a 14-day diary after surgery (60 in bowel preparation group, 61 in control group).	
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported.	
Other bias	Low risk	Appears free of other biases	

#### Barber 2014

Methods Trial design: multi-centre, 2 × 2 factorial randomised controlled trial	
Participants	Number of women randomised: 374 women (186 to behavioural therapy and pelvic BPMT (Barber 2014; McClurg 2014; Pauls 2013); 91 further randomised to receive ULS as the surgical intervention, 95 to receive SSLF, and 188 usual care (97 further randomised to receive ULS as surgical intervention and 91 to receive SSLF)

Number of women analysed: surgical outcome: ULS group, 155 women analysed; SSLF group, 149 women analysed; BPMT group, 153 analysed; usual care group, 164 women analysed

Mean age: BPMT group 57.5 years (SD 10.9), usual care group 56.9 years (SD 10.9)

Inclusion criteria: women aged > 18 years undergoing vaginal surgery for stage 2 through 4 prolapse (vaginal or uterine descent 1 cm proximal to the hymen or beyond) with complaints of vaginal bulge symptoms, descent of uterus of vaginal apex at least halfway into the vagina, stress incontinence symptoms, and objective demonstration of stress incontinence by office or urodynamic testing in the previous 12 months. Able to complete 24-month follow-up and study assessment

Exclusion criteria: contraindication to pelvic surgery, history of previous surgery that included SSLF or ULS, pelvic pain or dyspareunia due to levator ani spasm that would preclude a BPMT programme, history of previous synthetic sling procedure for stress incontinence, current or previous ureteral diver-



#### Barber 2014 (Continued)

ticulum, history of femoral-to-femoral bypass, current cytotoxic chemotherapy or current or history of pelvic radiation therapy, history of hospitalisation for medical comorbidities in previous 12 months

Setting: 9 sites throughout the USA

Timing: January 2008 to May 2013

#### Interventions

Intervention: BPMT group received an individualised programme that included 1 visit 2 to 4 weeks before surgery and 4 postoperative visits (2, 4 to 6, 8, and 12 weeks following surgery) that involved pelvic floor muscle training, individualised progressive pelvic floor muscle exercise, and education on behavioural strategies to reduce urinary and colorectal symptoms, which were performed at each visit. Self-reported adherence to BPMT was assessed at 6, 12, and 24 months. Visits were conducted by practitioners, all of whom had attended centralised in-person training before the start of the trial, +/- SSLF or ULS surgical procedure (n = 186).

Comparison: usual perioperative care, consisting of routine perioperative teaching and standardised postoperative instructions, +/- SSLF or ULS surgical procedure (n = 188)

#### Outcomes

#### **Primary outcome:** BPMT assessed at 6 and 24 months

Primary 6-month outcome was urinary symptoms assessed by the Urinary Distress Inventory (UDI) score of the Pelvic Floor Distress Inventory (PFDI). Primary 24-month outcomes were prolapse symptoms (assessed by the Pelvic Organ Prolapse Distress Inventory (POPDI) score of the PFDI) and anatomic failure (defined as one of the following: descent of vaginal apex more than one-third into the vaginal canal, anterior or posterior vaginal wall descent beyond the hymen, or retreatment for prolapse).

**Secondary outcomes:** maximum prolapse (anterior, posterior, and apical vaginal segments); retreatment for urinary incontinence, prolapse, or both; urinary, prolapse, and bowel symptoms (measured via PFDI, Incontinence Severity Index); pelvic floor muscle strength (measured by the Brink Grading System)

#### Notes

Intention-to-treat analysis: yes

Sample size calculation: yes. Sample size of 170 in each group was calculated to provide 80% power to detect a difference of 0.3 standard deviations in mean UDI score between BPMT and usual care groups, with a 2-tailed 5% level of significance. Anticipated recruiting 200 per group to allow for 15% dropout rate, but enrolment stopped after 374 participants were randomised, as early loss to follow-up was less than expected

Trial registration: ClinicalTrials.gov NCT00597935

Funding: supported by a number of grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Institutes of Health Office of Research on Women's Health

Several trial authors disclosed that they received research grants, royalties, or consulting fees from pharmaceutical companies, none of which are directly related to this study.

Detailed protocol for this trial was published in the journal Contemporary Clinical Trials 2009;30:178-89.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were assigned by the data co-ordinating centre according to a random permuted block design.
Allocation concealment (selection bias)	Low risk	Sequentially numbered, sealed opaque envelopes



Barber 2014 (Continued)		
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Owing to the nature of the behavioural intervention, blinding of participants or study personnel was not possible.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded to group allocation for surgical intervention and behavioural treatment. Patient-completed questionnaires were utilised.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up at 2 years  BMPT group: 33  Usual care group: 24
Selective reporting (reporting bias)	Low risk	All prespecified outcomes are reported.
Other bias	Low risk	Appears free of other sources of bias

### Billquist 2017

Methods	Single-centre constrained randomisation with allocation concealment			
Participants	44 enrolled and randomised: 23 to the GIM group and 21 to the control group			
	39 randomised and underwent surgery: 19 to preoperative guided imagery (GIM); 20 to standard care			
	Inclusion criteria: routine vaginal or laparoscopic pelvic floor surgery, > 1 week from enrolment, planned overnight admission, commitment to a 15-minute audio CD daily and proficiency in English			
	Location: Loyola University Chicago			
	Time: July 2014 to October 2015			
Interventions	GIM preoperative pelvic floor surgery; reviewed 15-minute CD developed by experienced behavioural specialist in family medicine to prepare for surgery			
	Standard care: included usual preoperative pathway without GIM CD			
Outcomes	Evaluated at day of surgery:			
	Anxiety: validated State-Trait Anxiety Inventory (STAI)			
	Preparedness: unvalidated Likert scale 0 to 10			
	POPQ examination			
	Pelvic floor distress Inverntory (PFDI)			
	Evaluated at 6 weeks:			
	Evaluated at 6 weeks:			
	<b>Evaluated at 6 weeks:</b> As above with Patient Global Impression of Improvment (PGI-I) and satisfaction on unvalidated Likert scale 0 to 10			



Bill	quis	t 2017	(Continued)
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Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Constructive randomisation	
Allocation concealment (selection bias)	Low risk	Stated allocation concealment without clarification	
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Unable to be blinded	
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated	
Incomplete outcome data (attrition bias) All outcomes	Low risk	GIM group: 18/19 completed 6-week review; standard care control group: 20/20 completed 6-week review	
Selective reporting (reporting bias)	Low risk	None	
Other bias	Low risk	None	

### **Bray 2017**

Single-centre randomised controlled trial				
Post void residual urine volume measured by abdominal ultrasound; bladder volume (mL) = depth $\times$ height (sagittal axis) $\times$ width (transverse axis) $\times$ 0.7				
Number of women randomised: 60 women (31 immediate catheter removal group, 29 SPC group)				
Inclusion criteria: admitted for prolapse surgery via vaginal route				
Exclusion criteria: contraindication for suprapubic catheter, inability to give informed consent, concomitant continence procedure (mid-urethral slings, colposuspension, Kelly plication sutures), preoperative voiding dysfunction, preoperative UTI, intraoperative bladder or bowel injury, requirement for vaginal packing or severe haemorrhage necessitated postoperative monitoring of urinary output				
Group A: immediate catheter removal as soon as surgery was completed. Patients were encouraged to void as soon as they felt a sense of urge. At 8 hours postoperatively, if the patient had not passed urine, then in/out catheterisation was performed and was repeated every 8 hours or sooner if the patient felt uncomfortable or was unable to void on 2 occasions. Patients were deemed to have completed the voiding trial once the voided volume was > 200 mL and the residual was consistently < 100 mL and comfortable.				
Group B: SPC Bonanno suprapubic catheter placed intraoperatively (this was on free drainage until day 2 postoperatively, when it was clamped and patients were encouraged to void spontaneously), passed the post void test if urine residual was < 100 mL (otherwise the SPC was left unclamped overnight and patient renewed TOV)				
Both groups received intraoperative prophylactic antibiotics.				
UTI (positive urine culture > 10 <sup>5</sup> CFU/mL associated with symptoms)				



#### Bray 2017 (Continued)

Notes

Many patients undergoing POP procedures require vaginal pack or have a concomitant continence procedure; the results are not applicable for these patients. Therefore this study is relevant only to a relatively small group of patients undergoing POP procedures.

### Risk of bias

Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Randomisation was performed with sealed, sequentially numbered, opaque envelopes. A computer-generated variable block size was used for randomisation.	
Allocation concealment (selection bias)	Low risk	Envelopes were prepared by an independent researcher at the time of surgery.	
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Masking of the physician or the patient to the assignment was not feasible given the nature of the intervention.	
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were subjective (UTI, day of mobilisation, length of stay).	
Incomplete outcome data (attrition bias) All outcomes	Low risk	None	
Selective reporting (reporting bias)	Low risk	None	
Other bias	Low risk	Appears free of other biases	

### Chan 2014

Methods	Trial design: single centre, parallel-arm randomised controlled trial
Participants	Number of women randomised: 93 (46 in preoperative stent group, 47 in no stent group)
	Number of women analysed: postoperative analysis conducted on 45 women in the preoperative stend group and in 46 in the no stent group
	Mean age: not stated
	Inclusion criteria: women with stage II to IV pelvic organ prolapse undergoing apical uterosacral ligament suspension (USLS) with or without total vaginal hysterectomy
	Exclusion criteria: not stated
	Setting: Santa Rosa, California, USA
	Timing: April 2010 to November 2013
Interventions	Intervention group: ureteral stent placement in the operating room before USLS surgery
	Comparison group: no ureteral stent placement before surgery



C	han	20	114	(Continued)

Outcomes

**Primary outcome:** intraoperative ureteral injury with kinking or obstruction during USLS, assessed by administering intravenous blue dye with cystoscopy to confirm bilateral efflux from both ureteral orifices following tying of the suspension sutures

Secondary outcomes: not stated

Notes

Intention-to-treat analysis: unclear

Sample size calculation: not stated

Trial registration: not stated

Funding: not stated

Study authors have no conflicts of interest to disclose.

#### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomised using a dynamic allocation approach" - no details of sequence generation
Allocation concealment (selection bias)	Unclear risk	No details of allocation concealment
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Described as single-blinded - no further details
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Described as single-blinded - no further details
Incomplete outcome data	High risk	One woman from each group was excluded from analysis:
(attrition bias) All outcomes		$\boldsymbol{1}$ procedure was aborted owing to dense adhesions, and $\boldsymbol{1}$ did not require a vault fixation
		Data for 1-month postoperative follow-up available for 37/45 in the stent group (17% loss to follow-up) and for 21/46 in the no stent group (55% loss to follow-up)
Selective reporting (reporting bias)	Low risk	Prespecified primary outcome reported
Other bias	High risk	Conference abstract only

## Dieter 2014

Methods	Trial design: single-centre, parallel-arm randomised controlled trial		
Participants	Number of women randomised: 163; nitrofurantoin n = 82, placebo n = 81		
	Number of women analysed: 159; nitrofurantoin n = 81, placebo n = 78		
	Mean age: nitrofurantoin 57 years (SD 13), placebo 57 years (SD 13)		



#### Dieter 2014 (Continued)

Inclusion criteria: women undergoing any POP surgery or mid-urethral sling or both and discharged with Foley catheter or intermittent self-catheterisation or hospitalised overnight with a transurethral Foley catheter

Exclusion criteria: women undergoing mesh excision surgery, urethral diverticulum, fistula repair, or sacral neuromodulation, intraoperative urinary tract injury requiring prolonged catheterisation, successful trial of void on the day of surgery and no requirement for catheterisation, pregnancy, younger than 21 years old, allergy to nitrofurantoin, creatinine clearance < 60 mL/min, preoperative urine voiding dysfunction, non-English speaking

Setting: Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, North Carolina, USA

Timing: August 2011 to February 2013

Interventions

Intervention: nitrofurantoin 100 mg orally, once daily for duration of catheterisation, up to 7 days

Comparison: identical-looking placebo tablet, once daily for duration of catheterisation, up to 7 days

Outcomes

**Primary outcome:** treatment for clinically suspected (development of urinary symptoms) or culture-proven UTI (> 100,000 colony-forming units of a single organism) within 3 weeks of surgery

**Secondary outcomes:** risk factors for treatment for postoperative UTI, bacterial resistance to nitrofurantoin on postoperative urine cultures

Notes

Intention-to-treat analysis: yes

Sample size calculation: yes. Sample size of 156 participants was calculated to provide 80% power to detect a reduction in risk of UTI from 30% to 10% with a 0.05 level of significance

Trial registration: ClinicalTrials.gov NCT01450800

Funding: supported by the Charles Hammond Research Fund, Department of Obstetrics and Gynecology, Duke University Medical Center

Study authors did not report any potential conflicts of interest.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation was conducted by the Duke University Medical Center Investigational Drug Services Pharmacy through random permutated blocks of 10 participants each. Actual method used to generate the random sequence was not stated.
Allocation concealment (selection bias)	Unclear risk	Method used to conceal group allocation was not stated.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Low risk	Study participants and healthcare providers were blinded to treatment allocation by the use of masked study drug and identical placebo dispensed by the Duke University Medical Center Investigational Drug Services Pharmacy. Each participant received a vial of 7 unmarked study drug capsules.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No details were provided of blinding of outcome assessors; however primary outcome was treatment for clinically suspected or culture-proven UTI within 3 weeks of surgery.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants randomised to nitrofurantoin received allocated treatment.  One participant in this group was excluded from analysis as was randomised twice in error. 78 of the 81 participants randomised to placebo received al-



Dieter 2014 (Continued)		located treatment. Three participants did not take medication home on discharge.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported.
Other bias	Unclear risk	Study authors mention conducting subanalyses that did not change the results of the study but remain unpublished.

### **Hakvoort 2011**

Methods	Multi-centre randomised controlled trial		
Participants	Number randomised: N = 87 (147 assessed for eligibility, 16 refused to participate, 38 were not asked to participate, 1 was excluded, 16 refused)		
	Intervention group (clean intermittent catheterisation - CIC): n = 45		
	Control group (transurethral indwelling catheterisation - TIC): n = 42		
	Patients older than 18 years experiencing abnormal post void residual (PVR) following vaginal prolapse surgery		
	Exclusion criteria: neurological or anxiety disorder, concomitant continence procedure		
Interventions	Intervention group: clean intermittent catheterisation (CIC-SpeediCath) performed by nursing staff/CISC. Catherisation with maximum interval of 6 hours		
	Control group: IDC (14 French silicone catheter) for 3 days		
	All participants received prophylactic antibiotics during surgery. A 14 French silicone transurethral indwelling catheter (IDC) and a vaginal gauze were inserted directly after surgery. IDC was removed on POD 1, urine residual was > 150 mL (measured by bladder scan) after first void defined as abnormal PVR.		
	Participants were allowed to go home with an indwelling catheter or, when able to self-catheterise, with instructions to perform clean intermittent self-catheterisation.		
	In the case of a persistent abnormal PVR after the initial period of 3 days, the surgeon was free to continue treatment by either IDC or CIC.		
Outcomes	Primary outcome: bacteriuria. Significant bacteriuria was defined as > 10 <sup>5</sup> colony-forming units in a culture. Culture was taken from the first void after PVR had normalised to < 150.		
	Secondary outcomes: UTI (bacteriuria, combined with 1 or more: fever, urinary frequency (more than 7 voids a day), dysuria, or lower abdominal pain), duration of catheterisation until normalisation of PVR, number of introductions of the catheter, duration of hospital stay, pain scores, difficulty with catheter use, patient satisfaction (assessed using visual analogue scores - patients were asked to put an 'X' on a 10-cm line, ranging from 0 to 100 between the 2 extremes, and the distance from the beginning of the line to the 'X' was measured)		
Notes	Netherlands		
Risk of bias			
Bias	Authors' judgement Support for judgement		



Hakvoort 2011 (Continued)		
Random sequence generation (selection bias)	Low risk	Computerised block randomisation was performed by the attending residents or gynaecologists.
Allocation concealment (selection bias)	Low risk	The allocation ratio was 1:1. All participants received the allocated intervention, and nobody pulled out of the study.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not possible
Incomplete outcome data (attrition bias) All outcomes	Low risk	None
Selective reporting (reporting bias)	Low risk	None
Other bias	Low risk	Patients were informed about the study preoperatively, and written informed consent was obtained.

## Henn 2016

Methods	Trial design: single-centre, parallel-arm randomised controlled trial		
Participants	Number randomised: 80; ornipressin group n = 40, normal saline placebo group n = 40		
	Number analysed: ornipressin group $n=40$ , saline placebo group $n=36$ (3 excluded for incomplete data and 1 had ineligible surgery)		
	Mean age: ornipressin 55.8 years (SD 9.14), saline placebo 56.9 years (SD 9.37)		
	Inclusion criteria: women undergoing vaginal pelvic organ prolapse repair under general anaesthesia with or without mesh augmentation		
	Exclusion criteria: use of regional anaesthesia, abdominal-vaginal surgery, previous prolapse surgery with mesh augmentation		
	Setting: Department of Obstetrics and Gynaecology, University of the Free State, Bloemfontein, South Africa		
	Timing: January 2013 to June 2013		
Interventions	Intervention: 80 mL of 5 IU of the vasoconstrictor ornipressin (vasopressin analogue) mixed into 100 mL of normal saline, resulting in a concentration of 0.05 IU/mL for use as a hydrodissection solution (per vaginal compartment)		
	Comparison: 80 mL normal saline alone (per vaginal compartment)		
Outcomes	<b>Primary outcomes:</b> intraoperative blood loss, calculated as the sum of weight of the surgical swabs used $(1 \text{ g} = 1 \text{ mL})$ and volume of blood in the aperture pouch and the suction canister		



Henn 2016 (Continued)	<b>Secondary outcomes:</b> cardiovascular parameters, assessed by recording blood pressure and pulse rate in the theatre before anaesthesia, intraoperatively after administration of the study solution, and on arrival to the recovery room after surgery
Notes	Intention-to-treat analysis: no
	Sample size calculation: A sample size calculation was not possible owing to lack of published information, and a convenience sample size of 80 participants was decided upon
	Trial registration: not stated.
	Funding: not stated. Study drug was manufactured by Por-8, Ferring, South Africa. Study authors state no potential conflicts of interest.

## Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomisation list generated by Department of Biostatistics
Allocation concealment (selection bias)	Low risk	Sequential, sealed envelopes
Blinding of participants and personnel (perfor- mance bias) All outcomes	Low risk	Participants were blinded to group allocation. Scrub nurses in the theatre prepared the study solution to maintain blinding of surgeons.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details of blinding of outcomes assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	All women randomised to the ornipessin group were analysed. Four women in the saline placebo group (3 with incomplete data collection and 1 with an ineligible surgery method) were excluded from analysis.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported.
Other bias	Low risk	None detected

## Kamilya 2010

Methods	Single-centre RCT
Participants	200 patients underwent randomisation, 100 to each group; 2 exclusions in intervention group and 1 in control group
	Inclusion criteria: patients undergoing vaginal prolapse surgery
	Exclusion criteria: women for whom complicated surgical procedure was anticipated (long-standing prolapse with severe fibrosis), prolapse surgery associated with plan of bladder or vault suspension or repair by mesh (expected to have higher rate of urinary retention), only posterior colporrhaphy, preoperative UTI
Interventions	Intervention: catheter removed on POD 1 and patient failed TOV if urine residual > 150 mL, recatheterisation until POD 4 (n = 98)



Kamil	ya 2010	(Continued)
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Control: catheter removed on POD 4 (n = 99)

All participants received 2 doses of antibiotic injection ceftriaxone (1 g) - 1 just before the operation and another dose 12 hours after the first dose.

All participants underwent surgery under spinal anaesthesia.

Residual urine over 150 mL (ultrasound scan) required recatheterisation.

Sample of urine was sent for culture during catheter removal.

Outcomes

Primary outcome: rate of recatheterisation

**Secondary outcomes:** length of hospital stay (time from completion of surgery to hospital discharge), urinary tract infection (positive urine culture taken from catheter before removal of  $> 10^5$  CFU/mL plus dysuria/fever > 38.5/rigors)

Notes

August 2005 to December 2007

India

#### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation list drawn up by a statistician
Allocation concealment (selection bias)	Low risk	Assignments were placed in sealed, serially numbered opaque envelopes and were revealed only after the operative procedure had ended.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Low risk	Not possible; not expected to have any effect on the outcome measures
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not possible; not expected to have any effect on the outcome measures
Incomplete outcome data	Low risk	Intervension group: 98/100 completed the study (2 excluded)
(attrition bias) All outcomes		Control group: 99/100 completed (1 excluded)
Selective reporting (reporting bias)	Low risk	None
Other bias	Low risk	None detected

### McClurg 2014

Methods	Trial design: multi-centre (3 sites), parallel-arm randomised controlled feasibility trial
Participants	Number randomised: 57 (perioperative pelvic floor muscle training group n = 28, control group n = 29)
	Number analysed: at 6-month follow-up treatment group $n=23$ , control group $n=25$ ; at 12-month follow-up, treatment group $n=14$ , control group $n=13$



Mc	CI	lurg	2014	(Continued)
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Mean age: no demographic details provided

Inclusion: women attending the gynaecological clinic at University Hospitals in any of the specified lo-

cations

Exclusion: not stated

Setting: hospitals in Glasgow (Scotland), Newcastle and Southhamptom (England), and Belfast (North-

ern Ireland)

Timing: not stated

Interventions

Intervention: pelvic floor muscle training programme following surgery to correct pelvic organ pro-

lapse

Comparison: control group of women who received no specific pelvic floor exercise direction (1 preop-

erative and 6 postoperative sessions)

All participants received post-surgery information sheet containing lifestyle advice, including avoid-

ance of heavy lifting and constipation, use of correct defecation technique and bracing.

All participants completed questionnaires at baseline (immediately before randomisation) and at 6

months and 12 months after randomisation.

Outcomes

**Primary outcome:** prolapse symptom severity measured by the Pelvic Organ Prolapse Symptom Score

Questionnaire (POP-SS) at 12 months

**Secondary outcomes:** urinary and bowel symptoms and sexual and general health (measured on International Consultation on Incontinience Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF) and Bowel Symptom (ICIQ-BS) Questionnaires, POP/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12), and Short Form Health Survey (SF-12)), degree of prolapse on the POP Quantification (POPQ) scale, and digital pelvic floor muscle evaluation via the Modified Oxford Scale and the PER-FECT Scale (P = pre-presenting power (or pressure, a measure of strength obtained by a manometric perineometer), E = endurance, R = repetitions, F = fast contractions, ECT = every contraction timed)

Notes

Intention-to-treat analysis: yes

Sample size calculation: not performed as this was a pilot study (provides recommended sample size

for future trials based on this study's results)

Trial registration: no details of trial registration

Funding: Physiotherapy Research Foundation

One study author disclosed receiving research grants from pharmaceutical companies, none of which are directly related to this study. Another study author is a speaker for several pharmaceutical companies and is on the Advisory Board of a pharmaceutical company. Two study authors had no financial

disclaimers or conflicts of interest.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomized using a remote computer programme"
Allocation concealment (selection bias)	Low risk	Quote: "remote computer programme that sent an email with the group allocation of the participant to the researcher, using the identification code initially assigned to the participant"



McClurg 2014 (Continued)		
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Owing to the nature of the intervention, participants and study personnel were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome examiner physiotherapist was blinded to group allocation.
Incomplete outcome data	High risk	Treatment group
(attrition bias) All outcomes		Did not complete 6-month questionnaire: 5 women (18%)
		Did not complete 12-month questionnaire: 14 women (50%)
		Did not attend 6-month POPQ and PFM review appointment: 14 women (50%)
		Did not attend 12-month POPQ and PFM review appointment: 23 women (82%)
		Control group
		Did not complete 6-month questionnaire: 4 women (14%)
		Did not complete 12-month questionnaire: 16 women (56%)
		Did not attend 6-month POPQ and PFM review appointment: 18 women (62%)
		Did not attend 12-month POPQ and PFM review appointment: 24 women (83%)
Selective reporting (reporting bias)	Low risk	All prespecified outcomes are reported.
Other bias	Unclear risk	Appears free of other sources of bias

### **Pauls 2013**

Methods	Trial design: single-centre, parallel-arm randomised controlled trial
	That design single centre, paraties and randomised controlled that
Participants	Number randomised: 57 women (pelvic floor physical therapy n = 29, control n = 28)
	Number analysed: 49 women (pelvic floor physical therapy n = 24, control n = 25)
	Mean age: pelvic floor physical therapy group 58.9 years (SD 10.66), control group 57.1 years (SD 10.41)
	Inclusion criteria: > 18 years of age, planning surgical correction to include vaginal native tissue reconstructive repair with or without a vaginal hysterectomy
	Exclusion criteria: planned use or intraoperative placement of vaginal mesh or graft; abdominal, robotic, or laparoscopic prolapse repair; concurrent surgery for genitourinary fistula; ureteral diverticulum or faecal incontinence such as anal sphincteroplasty; unable to comply with pelvic floor physical therapy or to complete questionnaires; pre-existing neurological conditions
	Setting: Department of Obstetrics and Gynecology, TriHealth Good Samaritan Hospital, Cincinnati, Ohio, USA
	Timing: July 2009 to November 2011



#### Pauls 2013 (Continued)

#### Interventions

Intervention: pelvic floor physical therapy sessions at 2 weeks before surgery, then 2, 4, 6, 8, and 12 weeks postoperatively. Sessions included information and training on pelvic floor exercises and relaxation, teaching regarding bladder and bowel function, pain management, core exercises, and scar tissue mobilisation. Sessions were designed by 2 experienced pelvic floor physical therapists and occurred in conjunction with a physician's assessment.

Control: no physical therapy, but attendance at appointments with the physician at all the same postoperative time points for physical examination and routine questioning

#### Outcomes

**Primary outcome:** change in the World Health Organization Quality of Life-BREF scale after surgery (WHOQOL-BREF). This is an abbreviated version of the WHOQOL-100, which measures an individual's quality of life on a scale of zero to 100. Higher scores are associated with better quality of life. Twenty-six questions evaluate 4 domains: physical, psychological, social, and environmental.

**Secondary outcomes:** subjective measurements of pelvic floor dysfunction, sexual function, postoperative pain, activity scales (using the Pelvic Floor Distress Inventory Questionnaire (PFDI), the Pelvic Floor Impact Questionnaire (PFIQ), the Short Form Health Survey-12 (SF-12), the Female Sexual Function Index, and the short form of the Prolapse and Incontinence Sexual Questionnaire (PISQ-12)), and pelvic floor and muscle function (using intravaginal electromyography (EMG)). Activity Assessment Scales (AAS) and Surgical Pain Scales (SPS) were also used at 2 and 6 weeks postoperatively.

#### Notes

ITT analysis: no

Sample size calculation: yes. Sample size of 50 participants was calculated to provide 80% power to detect a change in the WHOQOL-BREF and allowing for attrition.

Trial registration: ClinicalTrials.gov NCT01403701

Funding: Medical Education Research Fund, TriHealth Good Samaritan Hospital, Cincinnati, Ohio, USA

Study authors declare no conflicts of interest.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of generating the randomisation sequence not stated: "the sequentially numbered randomisation schedule was held by the research nurse who allocated patients to the next lowest unused subject identification number"
Allocation concealment (selection bias)	Unclear risk	No details provided on method used to conceal allocation
Blinding of participants and personnel (perfor- mance bias) All outcomes	High risk	Blinding of participants and study personnel was not possible owing to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No details were provided on blinding of outcome assessors; however validated questionnaires were used to measure outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two participants were excluded (1 received cancer diagnosis and 1 underwent an ineligible surgery); 3 withdrew (1 cancelled surgery and 2 had transportation difficulties) from intervention group and 3 withdrew from control group (1 cancelled surgery, 1 was uncomfortable with questionnaires, and 1 fractured her toes).
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported on.



Pauls 2013 (Continued)

Other bias Low risk Appears free of other sources of bias

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Methods	Trial design: single-centre, parallel-arm randomised controlled trial
Participants	Number randomised: 173 (vaginal pack group n = 86, no vaginal pack group n = 87)
	Number analysed for primary outcome of postoperative pain: pack group n = 84, no pack group n = 83
	Mean age: 58.3 years (range 27-91)
	Inclusion criteria: > 18 years of age, able to provide written consent in English, admission for elective vaginal hysterectomy and/or pelvic floor repair
	Exclusion criteria: deemed at higher risk of postoperative morbidity (e.g. clotting abnormalities, immunocompromised states, history of previous pelvic floor surgery)
	Setting: Urogynaecology Department, Kings College Hospital, London, United Kingdom
	Timing: October 2008 to January 2010
Interventions	Intervention: vaginal pack group received part or all of a 7.5-metre length of 10-cm-wide cotton gauze roll soaked in proflavine antiseptic solution packed tightly into the vaginal vault following surgery
	Comparison: no gauze packing following surgery
	All participants underwent vaginal hysterectomy and/or pelvic floor repair with or without vaginal vault suspension. All repairs were performed utilising native fascial tissue for repair, and no synthetic mesh was used. If the operating surgeon had surgical concerns, he/she could choose to place a pack in situ regardless of randomisation. All participants had an indwelling Foley catheter until the following morning.
Outcomes	<b>Primary outcome:</b> postoperative pain, assessed on day 1 at 7 am on the morning following surgery by means of the short-form McGill Pain Questionnaire
	<b>Secondary outcomes:</b> infective and haematological postoperative morbidity (assessed by comparing microbiological and haematological investigations (white blood cell count, high vaginal swab culture, midstream urine sample, haemoglobin and platelet counts)) assessed preoperatively vs assessments taken on day 2 and at 6 weeks postoperatively. Transvaginal ultrasound scan was also performed 6 weeks postoperatively to exclude pelvic haematoma in participants who underwent vaginal hysterectomy with or without pelvic floor repair.
Notes	ITT analysis: yes
	Sample size calculation: yes. Sample size of 86 in each group was calculated to provide 90% power to detect a clinically important difference in McGill Pain Questionnaire responses with an alpha error of 5%.
	Trial registration: no details
	Funding: "none" stated
	Several study authors declared receiving funding for research, lecturing, or consultancy from various pharmaceutical and medical technology companies.
Risk of bias	
Bias	Authors' judgement Support for judgement



Thiagamoorthy 2014 (Continue	ed)	
Random sequence generation (selection bias)	Unclear risk	No details were provided on the method used to generate the randomisation sequence.
Allocation concealment (selection bias)	Low risk	Opaque, sealed envelopes were used to conceal group allocation.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Study personnel and participants were blinded to group allocation until the primary outcome assessment was completed. However it is possible that participants may have been aware of the presence of the vaginal pack.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All staff subsequently involved in assessing secondary outcome measures were also blinded to the group allocation.
		Both researchers and patients were informed of patients' group assignment only after the pain questionnaire had been submitted to the ward sister.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up rate 91.5%
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported.
Other bias	Unclear risk	Patient-requested additional analgesia; time to mobilisation and duration of inpatient stay were not reported.

### Weemhoff 2010

Methods	Multi-centre randomised controlled trial		
Participants	Inclusion criteria: patients undergoing anterior colporrhaphy and concomitant continence or prolaps procedure allowed		
	Exclusion criteria: preop urinary voiding dysfunction requiring repeat catheterisations		
Interventions	Group 1: catheter removed on second postoperative day (n = 124)		
	Group 2: catheter removed on fifth postoperative day (n = 122)		
Outcomes	<b>Primary outcome:</b> number of temporary (~24 hours) catheter replacements after failed TOV (defined as urine residual > 200 mL measured by a bladder US scan)		
	Secondary outcomes: urinary tract infection, length of hospital stay		
Notes	Intention-to-treat		
	January 2006 to September 2008		
	3 hospitals in the Netherlands		

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A randomisation list was prepared by an independent statistician. Randomisation was performed in blocks and was stratified for different hospitals.



Weemhoff 2010 (Continued)		
Allocation concealment (selection bias)	Low risk	According to the randomisation list, opaque, numbered, and sealed envelopes were prepared by an independent person.
Blinding of participants and personnel (perfor- mance bias) All outcomes	Unclear risk	Blinding was not possible because of the character of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome measures are objective; therefore risk of detection bias was low.
Incomplete outcome data (attrition bias) All outcomes	Low risk	250 enrolled, 246 randomised, 246 analysed
Selective reporting (reporting bias)	Low risk	None detected
Other bias	Low risk	None detected

AAS: activity assessment scale.

BPMT: behavioural therapy with pelvic floor muscle training.

CFU: colony-forming unit.

CIC: clean intermittent catheterisation.

CISC: clean intermittent self-catheterisation.

EMG: electromyography. GIM: guided imagery.

ICIQ-BS: International Consultation on Incontinence Questionnaire Bowel Symptom.

ICIQ-UI SF: International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form.

IDC: indwelling catheter. ITT: intention-to-treat.

P-QOL= Prolapse Quality of Life Questionnaire.

PFDI: Pelvic Floor Distress Inventory. PFIQ: Pelvic Floor Impact Questionnaire.

PFM: pelvic floor muscle.

PGI-I: Patient Global Impression of Improvement.

PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.

POD: postoperative day. POP: pelvic organ prolapse.

POP-SS: Pelvic Organ Prolapse Symptom Score.

POPDI: Pelvic Organ Prolapse Distress Inventory.

POPQ: Pelvic Organ Prolapse Quantification.

PVR: post void residual. QoL: quality of life.

RCT: randomised controlled trial.

SD: standard deviation.

SF-12: Short Form Health Survey.

SPC: suprapubic catheter.

SPS: Surgical Pain Scale.

SSLF: sacrospinous ligament fixation.

STAI: State-Trait Anxiety Inventory.

 ${\sf TIC: transurethral\ indwelling\ catheter.}$ 

TOV: trial of voiding.

UDI: Urogenital Distress Inventory.

UI: urinary incontinence.

ULS: uterosacral ligament suspension.

US: ultrasound.

USLS: uterosacral ligament suspension.



UTI: urinary tract infection.

WHOQOL-100: tool that measures an individual's quality of life on a scale of zero to 100.

WHOQOL-BREF: abbreviated version of the WHOQOL-100.

## **Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
Bernades 2012	Bernardes and colleagues used ultrasonography to assess the effects of training programmes by measuring the cross-sectional area (CSA) of the levator ani muscle - non-surgery
Butler 2017	Assessed the impact of scopolamine and atropine on postoperative pain not directly relevant to prolapse procedures
Crisp 2012	Assessed the impact of patient-controlled analgesia (PCA); pain not directly relevant to prolapse procedures
Frawley 2010	Study population is not specific to prolapse procedures and included patients who underwent hysterectomy.
Glavind 2007	Glavind and colleagues compared 3 hours and 24 hours postoperative catheter removal following pelvic organ prolapse surgery. Although this study was very interesting, it was excluded from the review as there was a difference in rates of interventions between groups. Randomisation was performed with sealed envelopes opened at the end of the operation. 100% of patients undergoing enterocoele repair were allocated to the 24 hours group, whereas 84% of those undergoing vaginal hysterectomy and 62% undergoing vaginal hysterectomy with anterior repair were allocated to the 3 hours group.
Gungor 2014	Gungor and colleagues compared post void urine residuals 2, 3, and 4 days post anterior colporrhaphy. Distribution of types of operations and concomitant continence surgery was significantly different between groups.
Jabalameli 2012	Quasi-randomised study ("randomisation was by personnel (every second patient)"
Jarvis 2005	Included those undergoing incontinence and/or prolapse surgery.
Karp 2012	Assessed the impact of postoperative vaginal oestrogen on patient recovery; vaginal healing measures not included in outcomes
Pauls 2015	Assessed the impact of preoperative dexamethasone on patient recovery; nausea and vomiting not specific to prolapse procedures
Zhu 2014	Impact of preoperative vaginal oestrogen on mesh erosion covered by the mesh review

CSA: XXX. PSA: XXX.

## **Characteristics of studies awaiting assessment** [ordered by study ID]

#### Calderon 2015

Methods	Prospective experimental comparative and randomised study
Participants	Forty-four patients undergoing vaginal surgery for pelvic organ prolapse
Interventions	Hydrodissection with epinephrine (n = 22) or no hydrodissection with epinephrine (n = 22) before surgery



Calderon 2015 (Continued)	
Outcomes	Operative morbidity (infection, haematoma, and surgical postoperative bleeding requiring transfusion), surgical time required to complete the procedure
Notes	Data are not available for analysis.

### **Crisp 2017**

Methods	Double-blind placebo-controlled randomised trial. Block randomisation
Participants	Women scheduled for reconstructive surgery including vaginal hysterectomy and vaginal vault suspension
Interventions	1000 mg of intravenous acetaminophen (n = 47) or 100 mL of placebo (n = 43) every 6 hours for 24 hours
Outcomes	Postoperative pain, satisfaction with pain control
Notes	Data are not available for analysis.

### **Letko 2014**

Methods	Randomised double-blinded placebo-controlled pilot study
Participants	Women between 18 and 70 years of age who underwent vaginal surgery with apical and/or posterior repair
Interventions	Cyclobenzaprine 5 mg TID (n = 24) or placebo (n = 25) for 7 days following surgery in conjunction with standard postoperative pain medication regimen
Outcomes	Primary outcome: pain score on postoperative day 7
	<b>Secondary outcomes:</b> Wexner constipation scores, length of surgery, concomitant surgical procedures, intraoperative and postoperative complication rates, surgical satisfaction, total in-hospital opioid use
	opiola disc

### DATA AND ANALYSES

## Comparison 1. Pelvic floor muscle training before and after prolapse surgery vs usual care

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Awareness of prolapse	1	305	Odds Ratio (M-H, Fixed, 95% CI)	1.07 [0.61, 1.87]
2 Pelvic organ prolapse symptom score (POPSS)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

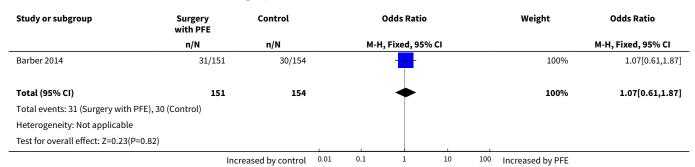


Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size		
2.1 6 months	1	48	Mean Difference (IV, Fixed, 95% CI)	0.20 [-2.18, 2.58]		
2.2 12 months	1	27	Mean Difference (IV, Fixed, 95% CI)	-3.90 [-6.11, -1.69]		
3 Objective failure any site (stage 2 or more)	2		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only		
3.1 Hymen or beyond anterior compartment	1	308	Odds Ratio (M-H, Fixed, 95% CI)	0.86 [0.44, 1.67]		
3.2 Hymen or beyond posterior compartment	1	308	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.15, 2.70]		
3.3 Hymen or beyond apical compartment	1	307	Odds Ratio (M-H, Fixed, 95% CI)	1.06 [0.15, 7.63]		
3.4 POP	2	327	Odds Ratio (M-H, Fixed, 95% CI)	0.93 [0.56, 1.54]		
4 Patient Global Impression of Improvement (PGI-I) much or very much better	1	964	Odds Ratio (M-H, Fixed, 95% CI)	1.01 [0.76, 1.33]		
4.1 PGI-I 6 months	1	336	Odds Ratio (M-H, Fixed, 95% CI)	1.09 [0.68, 1.75]		
4.2 PGI-I 12 months	1	324	Odds Ratio (M-H, Fixed, 95% CI)	0.82 [0.50, 1.35]		
4.3 PGI-I 24 months	1	304	Odds Ratio (M-H, Fixed, 95% CI)	1.12 [0.69, 1.81]		
5 Pelvic Organ Prolapse/Urinary Incontinence Sexual Question- naire (PISQ)	2	76	Mean Difference (IV, Fixed, 95% CI)	-0.78 [-4.12, 2.56]		
6 Short Form Health Survey (SF-12)	2	74	Mean Difference (IV, Fixed, 95% CI)	4.18 [1.25, 7.10]		
7 Postoperative prolapse symptoms (International Consultation on Incontinence Questionnaire)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only		
7.1 Urinary incontinence	1	27	Mean Difference (IV, Fixed, 95% CI)	-0.5 [-3.22, 2.22]		
7.2 Bowel symptoms	1	27	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-3.53, 1.93]		
8 Any treatment for SUI	1	273	Odds Ratio (M-H, Fixed, 95% CI)	1.09 [0.68, 1.76]		
9 Repeat surgery	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only		
9.1 Urinary incontinence	1	273	Odds Ratio (M-H, Fixed, 95% CI)	1.75 [0.56, 5.51]		
9.2 Surgery or pessary for recur- rent prolapse	1	316	Odds Ratio (M-H, Fixed, 95% CI)	1.92 [0.74, 5.02]		



Outcome or subgroup title	No. of studies No. of participants		Statistical method	Effect size
9.3 Surgery only for recurrent prolapse	1	316	Odds Ratio (M-H, Fixed, 95% CI)	0.86 [0.23, 3.26]
10 Modified Oxford Pelvic floor contraction grading (0-5)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
10.1 Power	1	10	Mean Difference (IV, Fixed, 95% CI)	1.1 [0.17, 2.03]
10.2 Repetitions	1	10	Mean Difference (IV, Fixed, 95% CI)	2.10 [-0.75, 4.95]
10.3 Endurance	1	10	Mean Difference (IV, Fixed, 95% CI)	-0.27 [-3.12, 2.58]
11 Hold with cough (Yes/No)	1	10	Odds Ratio (M-H, Random, 95% CI)	7.86 [0.28, 217.11]

Analysis 1.1. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 1 Awareness of prolapse.



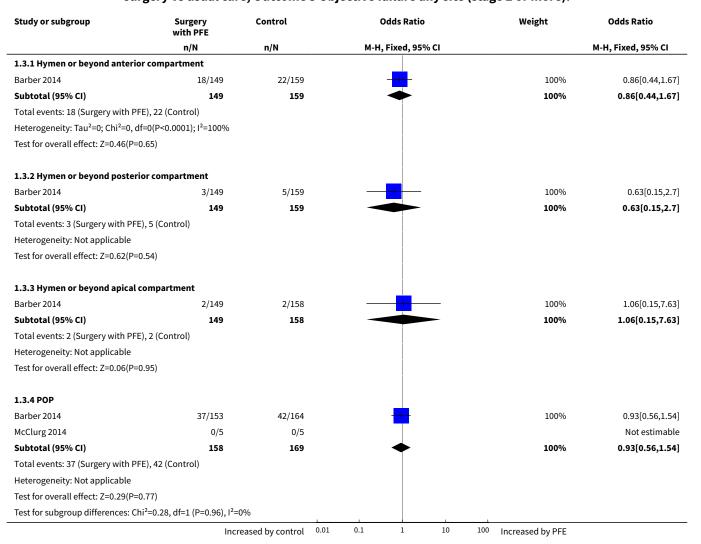
Analysis 1.2. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 2 Pelvic organ prolapse symptom score (POPSS).

Study or subgroup	Surgery with PFE		Control		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
1.2.1 6 months							
McClurg 2014	25	3.9 (4.5)	23	3.7 (3.9)	+	100%	0.2[-2.18,2.58]
Subtotal ***	25		23		<b>→</b>	100%	0.2[-2.18,2.58]
Heterogeneity: Not applicable							
Test for overall effect: Z=0.16(P=0.87	)						
1.2.2 12 months							
McClurg 2014	13	2.5 (2.4)	14	6.4 (3.4)	+	100%	-3.9[-6.11,-1.69]
Subtotal ***	13		14		<b>◆</b>	100%	-3.9[-6.11,-1.69]
Heterogeneity: Not applicable							
			Increas	sed by control	-20 -10 0 10 20	Increased b	y PFE



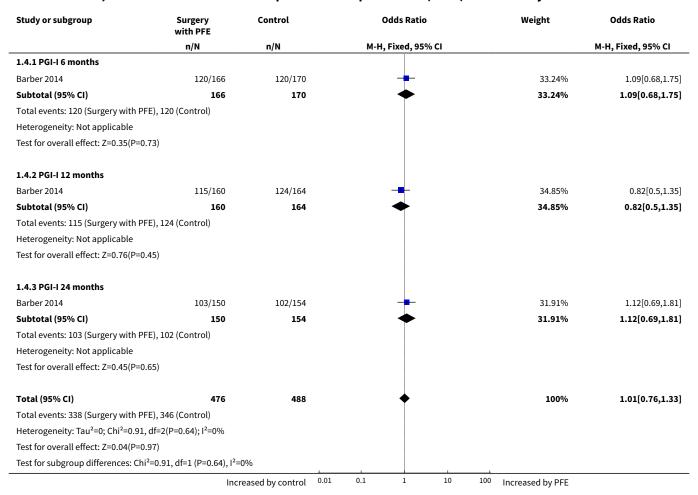
Study or subgroup	Surge	Surgery with PFE Control		Control	Mean Difference					Weight	Weight Mean Difference		
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI			Fixed, 95% CI					
Test for overall effect: Z=3.46(P=0	)												
Test for subgroup differences: Chi	i <sup>2</sup> =6.13, df=	1 (P=0.01), I <sup>2</sup> =83.	7%										
			Increa	ased by control	-20	-10	0	10	20	Increased by	PFE		

Analysis 1.3. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 3 Objective failure any site (stage 2 or more).





# Analysis 1.4. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 4 Patient Global Impression of Improvement (PGI-I) much or very much better.



Analysis 1.5. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 5 Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ).

Study or subgroup	Surge	Surgery with PFE		Control		Mean Difference			Weight		Mean Difference	
	N	Mean(SD)	N	Mean(SD)		F	ixed, 95% CI				Fixed, 95% CI	
McClurg 2014	13	31.1 (23.2)	14	29.4 (17.7)			+			4.55%	1.7[-13.95,17.35]	
Pauls 2013	24	35.5 (6.2)	25	36.4 (6)			+			95.45%	-0.9[-4.32,2.52]	
Total ***	37		39				•			100%	-0.78[-4.12,2.56]	
Heterogeneity: Tau <sup>2</sup> =0; Chi <sup>2</sup> =0	0.1, df=1(P=0.75	); I <sup>2</sup> =0%										
Test for overall effect: Z=0.46(	P=0.65)											
			Increas	ed by control	-100	-50	0	50	100	Increased by PFE		



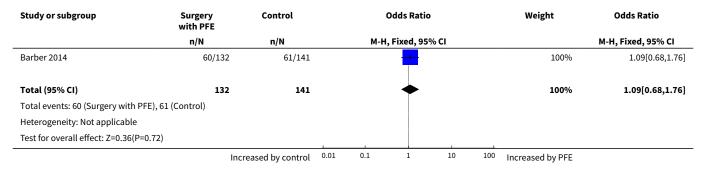
# Analysis 1.6. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 6 Short Form Health Survey (SF-12).

Study or subgroup	Surge	Surgery with PFE		Control		Mea	n Difference	Weight	Mean Difference	
	N	Mean(SD)	N	Mean(SD)		Fix	ed, 95% CI		Fixed, 95% CI	
McClurg 2014	13	42.6 (3.6)	14	35.7 (6.3)			-	58.11%	6.9[3.06,10.74]	
Pauls 2013	22	50.8 (7.6)	25	50.4 (8.2)			<u> </u>	41.89%	0.4[-4.12,4.92]	
Total ***	35		39				•	100%	4.18[1.25,7.1]	
Heterogeneity: Tau <sup>2</sup> =0; Chi <sup>2</sup> =	4.62, df=1(P=0.0	3); I <sup>2</sup> =78.35%								
Test for overall effect: Z=2.8(F	P=0.01)									
			Increas	sed by control	-20	-10	0 10 20	Increased b	y PFE	

# Analysis 1.7. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 7 Postoperative prolapse symptoms (International Consultation on Incontinence Questionnaire).

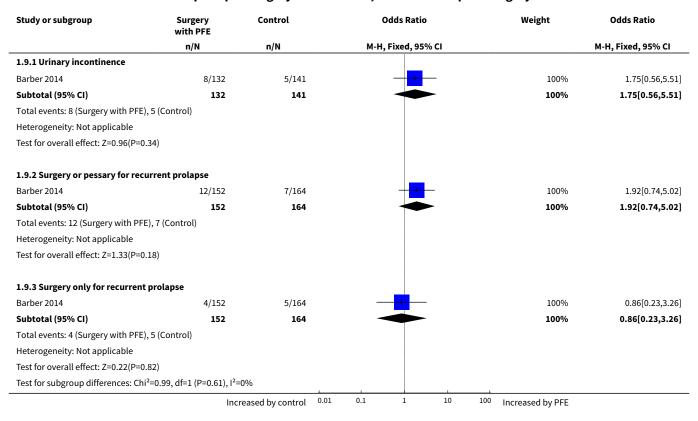
Study or subgroup	Surge	ry with PFE	c	ontrol		Ме	ean Difference		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		F	ixed, 95% CI			Fixed, 95% CI
1.7.1 Urinary incontinence										
McClurg 2014	13	2.8 (3.7)	14	3.3 (3.5)			+		100%	-0.5[-3.22,2.22]
Subtotal ***	13		14				<b>→</b>		100%	-0.5[-3.22,2.22]
Heterogeneity: Not applicable										
Test for overall effect: Z=0.36(P=0.7	72)									
1.7.2 Bowel symptoms										
McClurg 2014	13	11.6 (3.8)	14	12.4 (3.4)			+		100%	-0.8[-3.53,1.93]
Subtotal ***	13		14				<u></u> ★		100%	-0.8[-3.53,1.93]
Heterogeneity: Not applicable										
Test for overall effect: Z=0.57(P=0.5	57)									
Test for subgroup differences: Chi <sup>2</sup>	=0.02, df=1	L (P=0.88), I <sup>2</sup> =0%								
			Increas	sed by control	-100	-50	0	50 100	Increased by PF	E .

# Analysis 1.8. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 8 Any treatment for SUI.





Analysis 1.9. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 9 Repeat surgery.



Analysis 1.10. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 10 Modified Oxford Pelvic floor contraction grading (0-5).

Study or subgroup	Surge	ry with PFE	C	ontrol	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
1.10.1 Power							
McClurg 2014	5	3.5 (0.7)	5	2.4 (0.8)	<del>-</del>	100%	1.1[0.17,2.03]
Subtotal ***	5		5		•	100%	1.1[0.17,2.03]
Heterogeneity: Not applicable							
Test for overall effect: Z=2.31(P=0.02)							
1.10.2 Repetitions							
McClurg 2014	5	10 (2.3)	5	7.9 (2.3)	-	100%	2.1[-0.75,4.95]
Subtotal ***	5		5			100%	2.1[-0.75,4.95]
Heterogeneity: Not applicable							
Test for overall effect: Z=1.44(P=0.15)							
1.10.3 Endurance							
McClurg 2014	5	7 (2.4)	5	7.3 (2.2)	i	100%	-0.27[-3.12,2.58]
Subtotal ***	5		5			100%	-0.27[-3.12,2.58]
Heterogeneity: Not applicable							
Test for overall effect: Z=0.19(P=0.85)							
Test for subgroup differences: Chi <sup>2</sup> =1.	.35, df=1	L (P=0.51), I <sup>2</sup> =0%					



# Analysis 1.11. Comparison 1 Pelvic floor muscle training before and after prolapse surgery vs usual care, Outcome 11 Hold with cough (Yes/No).

Study or subgroup	Surgery with PFE	Control		Odds Ratio			Weight	Odds Ratio
	n/N	n/N		M-H, Ran	dom, 95% CI			M-H, Random, 95% CI
McClurg 2014	5/5	3/5				<b>-</b>	100%	7.86[0.28,217.11]
Total (95% CI)	5	5					100%	7.86[0.28,217.11]
Total events: 5 (Surgery with PFE	E), 3 (Control)							
Heterogeneity: Tau <sup>2</sup> =0; Chi <sup>2</sup> =0, d	If=0(P<0.0001); I <sup>2</sup> =100%							
Test for overall effect: Z=1.22(P=	0.22)							
	Incr	eased by control	0.01	0.1	1 10	100	Increased by PFE	

### Comparison 2. Preoperative guided imagery

Outcome or subgroup title	o title No. of studies No. of p pants		Statistical method	Effect size
1 Patient satisfaction	1	38	Mean Difference (IV, Fixed, 95% CI)	0.5 [-0.34, 1.34]
2 PFDI score change from baseline to 6 weeks	1	38	Mean Difference (IV, Fixed, 95% CI)	2.30 [-3.07, 7.67]

## Analysis 2.1. Comparison 2 Preoperative guided imagery, Outcome 1 Patient satisfaction.

Study or subgroup	Pre-opera- tive guidance		Usual care		Mean Difference			Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fixed	, 95% CI		Fixed, 95% CI
Billquist 2017	18	9.6 (0.9)	20	9.1 (1.7)				100%	0.5[-0.34,1.34]
Total ***	18		20				•	100%	0.5[-0.34,1.34]
Heterogeneity: Not applicable									
Test for overall effect: Z=1.16(P=0.24)									
			favo	urs usual care	-5	-2.5	0 2.5 5	favours pre	op guidance

Analysis 2.2. Comparison 2 Preoperative guided imagery, Outcome 2 PFDI score change from baseline to 6 weeks.

Study or subgroup	Pre-opera- tive guidance		Usual care			Mean Difference				Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fi	ixed, 95% CI				Fixed, 95% CI
Billquist 2017	18	26.2 (7.2)	20	23.9 (9.6)			+			100%	2.3[-3.07,7.67]
Total ***	18		20				•			100%	2.3[-3.07,7.67]
Heterogeneity: Not applicable											
			favoi	urs usual care	-100	-50	0	50	100	favours preo	p guidance



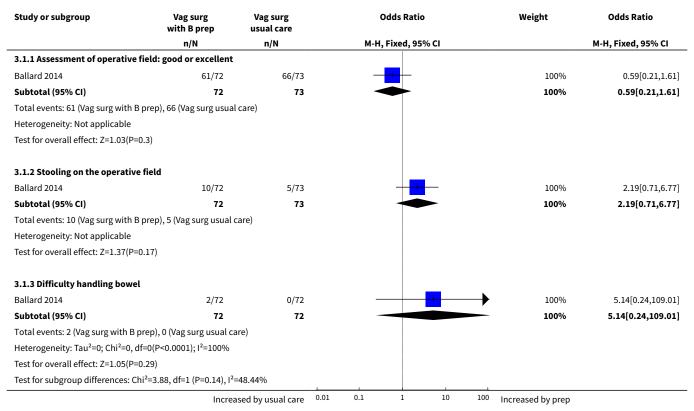
Study or subgroup	y or subgroup Pre-opera- tive guidance		U	sual care		Me	an Differe	nce	Weight Mean Difference	
	N	Mean(SD)	N	Mean(SD)		Fixed, 95% CI		Fixed, 95% CI		
Test for overall effect: Z=0.84(P=0.4)	rall effect: Z=0.84(P=0.4)			1						
			favo	ours usual care	-100	-50	0	50	100	favours preop guidance

## Comparison 3. Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Perioperative accessibility: before vaginal prolapse surgery	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Assessment of operative field: good or excellent	1	145	Odds Ratio (M-H, Fixed, 95% CI)	0.59 [0.21, 1.61]
1.2 Stooling on the operative field	1	145	Odds Ratio (M-H, Fixed, 95% CI)	2.19 [0.71, 6.77]
1.3 Difficulty handling bowel	1	144	Odds Ratio (M-H, Fixed, 95% CI)	5.14 [0.24, 109.01]
2 Mean time to first bowel movement	1	121	Mean Difference (IV, Fixed, 95% CI)	2.60 [-7.58, 12.78]
3 Perioperative accessibility: before vaginal prolapse surgery	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Assessment of operative field: good or excellent	1	145	Odds Ratio (M-H, Fixed, 95% CI)	0.59 [0.21, 1.61]
3.2 Stooling on the operative field	1	145	Odds Ratio (M-H, Fixed, 95% CI)	2.19 [0.71, 6.77]
3.3 Difficulty handling bowel	1	144	Odds Ratio (M-H, Fixed, 95% CI)	5.14 [0.24, 109.01]
4 Faecal leakage at first bowel movement	1	121	Odds Ratio (M-H, Fixed, 95% CI)	0.89 [0.32, 2.48]
5 Faecal urgency	1	121	Odds Ratio (M-H, Fixed, 95% CI)	1.11 [0.54, 2.26]
6 Pain first bowel movement	1	121	Odds Ratio (M-H, Fixed, 95% CI)	0.52 [0.21, 1.25]
7 Patient satisfaction related to bowel preparation (willing to have the same prep in the future)	1	143	Odds Ratio (M-H, Fixed, 95% CI)	0.25 [0.05, 1.27]



# Analysis 3.1. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 1 Perioperative accessibility: before vaginal prolapse surgery.



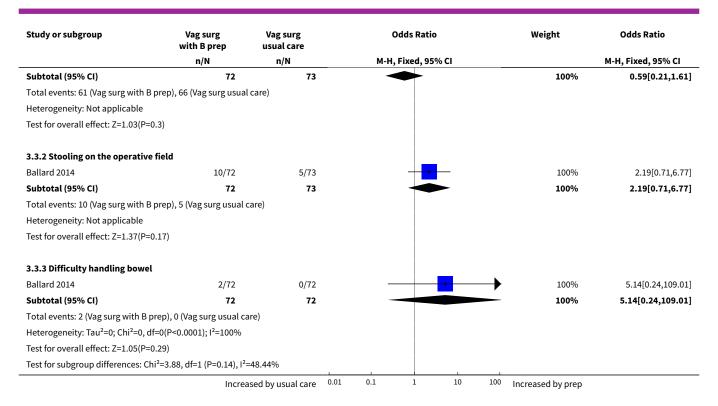
Analysis 3.2. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 2 Mean time to first bowel movement.

Study or subgroup	Vag surg with B prep		Vag surg usual care			Mean Difference				Weight N	Mean Difference
	N	Mean(SD)	N	Mean(SD)			Fixed, 95% C	l			Fixed, 95% CI
Ballard 2014	60	81.2 (28.9)	61	78.6 (28.2)						100%	2.6[-7.58,12.78]
Total ***	60		61				•			100%	2.6[-7.58,12.78]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.5(P=0.62)											
			Increased	by usual care	-100	-50	0	50	100	Increased by pre	p

Analysis 3.3. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 3 Perioperative accessibility: before vaginal prolapse surgery.

Study or subgroup	Vag surg with B prep	Vag surg usual care		Odds Ratio				Weight	Odds Ratio
	n/N	n/N		М-Н,	Fixed, 95%	% CI			M-H, Fixed, 95% CI
3.3.1 Assessment of operative	e field: good or excellent								
Ballard 2014	61/72	66/73						100%	0.59[0.21,1.61]
	Increas	sed by usual care	0.01	0.1	1	10	100	Increased by prep	





Analysis 3.4. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 4 Faecal leakage at first bowel movement.

Study or subgroup	Vag surg with B prep	Vag surg usual care			Odds Ratio			Weight	Odds Ratio
	n/N	n/N		M-I	H, Fixed, 95% (	CI			M-H, Fixed, 95% CI
Ballard 2014	8/60	9/61						100%	0.89[0.32,2.48]
Total (95% CI)	60	61						100%	0.89[0.32,2.48]
Total events: 8 (Vag surg with B pre	o), 9 (Vag surg usual ca	re)							
Heterogeneity: Not applicable									
Test for overall effect: Z=0.22(P=0.8	2)								
	Increa	sed by usual care	0.01	0.1	1	10	100	Increased by prep	

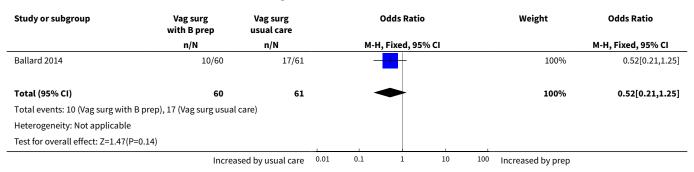
Analysis 3.5. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 5 Faecal urgency.

Study or subgroup	Vag surg with B prep	Vag surg usual care		Odds Ratio		Weight	Odds Ratio		
	n/N	n/N		М-Н,	Fixed, 9	5% CI			M-H, Fixed, 95% CI
Ballard 2014	33/60	32/61		_	-			100%	1.11[0.54,2.26]
Total (95% CI)	60	61		-		<b>-</b>		100%	1.11[0.54,2.26]
Total events: 33 (Vag surg with B	prep), 32 (Vag surg usual	care)							
Heterogeneity: Not applicable									
	Increa	sed by usual care	0.2	0.5	1	2	5	Increased by prep	

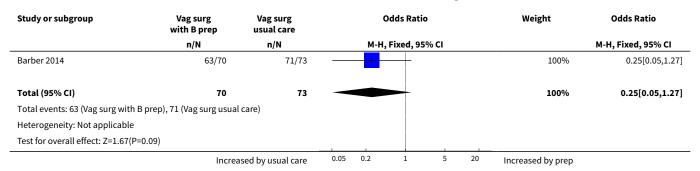


Study or subgroup	Vag surg with B prep	Vag surg usual care		0	dds Rat	io		Weight	Odds Ratio
	n/N	n/N		М-Н, І	ixed, 9	5% CI			M-H, Fixed, 95% CI
Test for overall effect: Z=0.28(P=0.78)									
	Incr	eased by usual care	0.2	0.5	1	2	5	Increased by prep	

# Analysis 3.6. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 6 Pain first bowel movement.



Analysis 3.7. Comparison 3 Bowel preparation before vaginal prolapse surgery vs no bowel preparation: vaginal route, Outcome 7 Patient satisfaction related to bowel preparation (willing to have the same prep in the future).



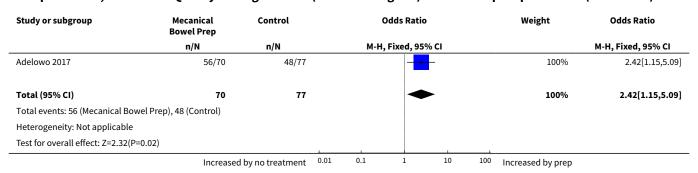
### Comparison 4. Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Quality of surgical field (excellent or good) after initial port placement (less is bad)	1	147	Odds Ratio (M-H, Fixed, 95% CI)	2.42 [1.15, 5.09]
2 Quality of surgical field (excellent or good) at the conclusion of surgery	1	147	Odds Ratio (M-H, Fixed, 95% CI)	1.88 [0.74, 4.74]
3 Large bowel assessment via intraoperative palpation and inspection (collapsed)	1	147	Odds Ratio (M-H, Fixed, 95% CI)	1.10 [0.57, 2.10]

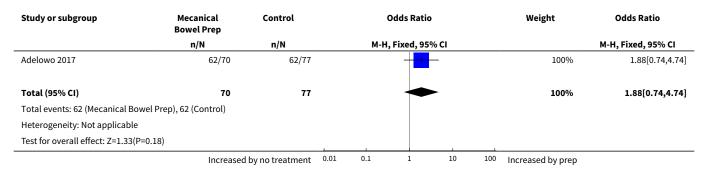


Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
4 Patient's willingness to have same bowel preparation again (less is bad)	1	149	Odds Ratio (M-H, Fixed, 95% CI)	0.17 [0.06, 0.48]
5 Faecal incontinence	1	149	Odds Ratio (M-H, Fixed, 95% CI)	0.17 [0.06, 0.48]
6 Hospital stays one night	1	148	Odds Ratio (M-H, Fixed, 95% CI)	1.89 [0.34, 10.65]

Analysis 4.1. Comparison 4 Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure, Outcome 1 Quality of surgical field (excellent or good) after initial port placement (less is bad).



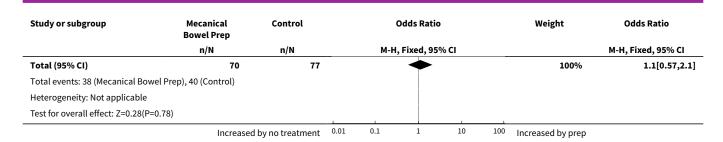
Analysis 4.2. Comparison 4 Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure, Outcome 2 Quality of surgical field (excellent or good) at the conclusion of surgery.



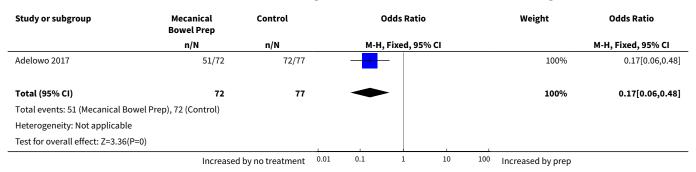
Analysis 4.3. Comparison 4 Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure, Outcome 3 Large bowel assessment via intraoperative palpation and inspection (collapsed).

Study or subgroup	Mecanical Bowel Prep	Control		Odds Ratio				Weight	Odds Ratio
	n/N	n/N		M-H	l, Fixed, 95	% CI			M-H, Fixed, 95% CI
Adelowo 2017	38/70	40/77	1	-				100%	1.1[0.57,2.1]
	Increased	by no treatment	0.01	0.1	1	10	100	Increased by prep	

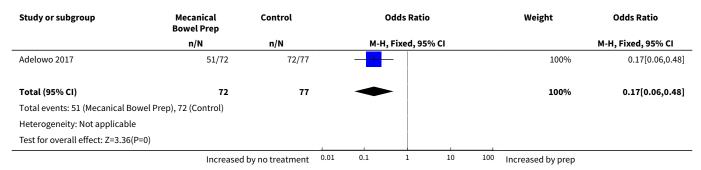




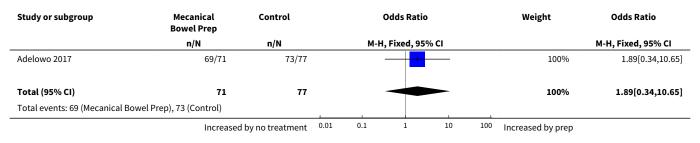
# Analysis 4.4. Comparison 4 Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure, Outcome 4 Patient's willingness to have same bowel preparation again (less is bad).



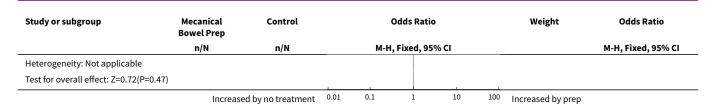
# Analysis 4.5. Comparison 4 Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure, Outcome 5 Faecal incontinence.



# Analysis 4.6. Comparison 4 Bowel preparation before vaginal prolapse surgery: laparoscopic or robotic procedure, Outcome 6 Hospital stays one night.







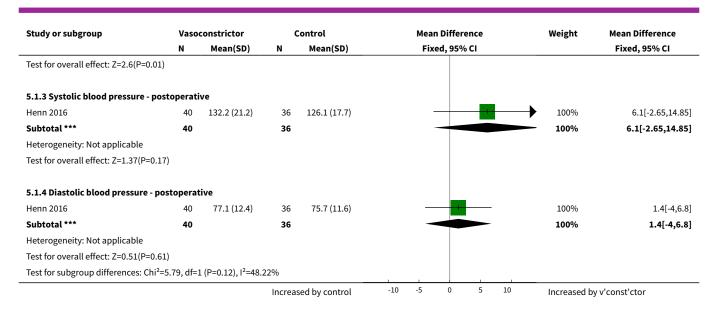
## Comparison 5. Injection of vasoconstrictor agent at commencement of vaginal prolapse surgery

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Blood pressure	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Systolic blood pressure - intraoperative	1	76	Mean Difference (IV, Fixed, 95% CI)	13.20 [5.07, 21.33]
1.2 Diastolic blood pressure - intraoperative	1	76	Mean Difference (IV, Fixed, 95% CI)	6.40 [1.58, 11.22]
1.3 Systolic blood pressure - postoperative	1	76	Mean Difference (IV, Fixed, 95% CI)	6.10 [-2.65, 14.85]
1.4 Diastolic blood pressure - postoperative	1	76	Mean Difference (IV, Fixed, 95% CI)	1.40 [-4.00, 6.80]
2 Heart rate	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Intraoperative heart rate	1	76	Mean Difference (IV, Fixed, 95% CI)	-3.30 [-10.90, 4.30]
2.2 Postoperative heart rate	1	76	Mean Difference (IV, Fixed, 95% CI)	-2.5 [-8.55, 3.55]
3 Blood loss	1	76	Mean Difference (IV, Fixed, 95% CI)	-29.60 [-56.57, -2.63]

# Analysis 5.1. Comparison 5 Injection of vasoconstrictor agent at commencement of vaginal prolapse surgery, Outcome 1 Blood pressure.

Study or subgroup	Vaso	constrictor	c	Control	Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI		Fixed, 95% CI
5.1.1 Systolic blood pressure - int	traoperati	ive					
Henn 2016	40	138.1 (17)	36	124.9 (19)		100%	13.2[5.07,21.33]
Subtotal ***	40		36			100%	13.2[5.07,21.33]
Heterogeneity: Not applicable							
Test for overall effect: Z=3.18(P=0)							
5.1.2 Diastolic blood pressure - in	itraoperai	tive					
Henn 2016	40	76.8 (8.6)	36	70.4 (12.3)		100%	6.4[1.58,11.22]
Subtotal ***	40		36			100%	6.4[1.58,11.22]
Heterogeneity: Not applicable							
			Increas	sed by control	-10 -5 0 5 10	Increased b	y v'const'ctor





Analysis 5.2. Comparison 5 Injection of vasoconstrictor agent at commencement of vaginal prolapse surgery, Outcome 2 Heart rate.

Study or subgroup	Vaso	constrictor	c	Control		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fixed, 95% CI		Fixed, 95% CI
5.2.1 Intraoperative heart rate								
Henn 2016	40	75.6 (17.6)	36	78.9 (16.2)		<del>-</del>	100%	-3.3[-10.9,4.3]
Subtotal ***	40		36			•	100%	-3.3[-10.9,4.3]
Heterogeneity: Not applicable								
Test for overall effect: Z=0.85(P=0.39	9)							
5.2.2 Postoperative heart rate								
Henn 2016	40	73.3 (12.7)	36	75.8 (14.1)		-	100%	-2.5[-8.55,3.55]
Subtotal ***	40		36			•	100%	-2.5[-8.55,3.55]
Heterogeneity: Not applicable								
Test for overall effect: Z=0.81(P=0.42	2)							
Test for subgroup differences: Chi <sup>2</sup> =	0.03, df=1	L (P=0.87), I <sup>2</sup> =0%						
			Increas	sed by control	-40 -20	0 20	40 Increased b	y v'const'ctor

Analysis 5.3. Comparison 5 Injection of vasoconstrictor agent at commencement of vaginal prolapse surgery, Outcome 3 Blood loss.

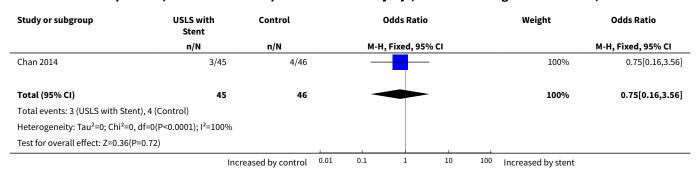
Study or subgroup	Vaso	constrictor	c	ontrol		Mea	n Differend	:e		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fix	ed, 95% CI	1			Fixed, 95% CI
Henn 2016	40	57.5 (55.9)	36	87.1 (63.3)		-				100%	-29.6[-56.57,-2.63]
Total ***	40		36							100%	-29.6[-56.57,-2.63]
Heterogeneity: Not applicable											
Test for overall effect: Z=2.15(P=0.03)											
			Increas	ed by control	-100	-50	0	50	100	Increased b	y v'const'ctor



### Comparison 6. Ureteral stent placement during uterosacral ligament suspension

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Intraoperative ureteral injury (ureteral kinking or obstruction)	1	91	Odds Ratio (M-H, Fixed, 95% CI)	0.75 [0.16, 3.56]

# Analysis 6.1. Comparison 6 Ureteral stent placement during uterosacral ligament suspension, Outcome 1 Intraoperative ureteral injury (ureteral kinking or obstruction).

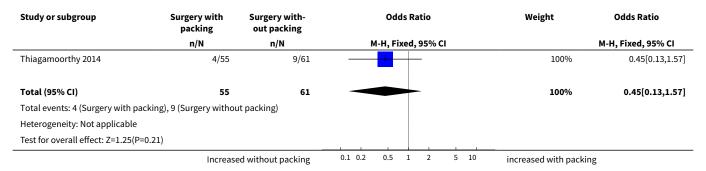


### Comparison 7. Vaginal pack insertion after pelvic organ prolapse surgery

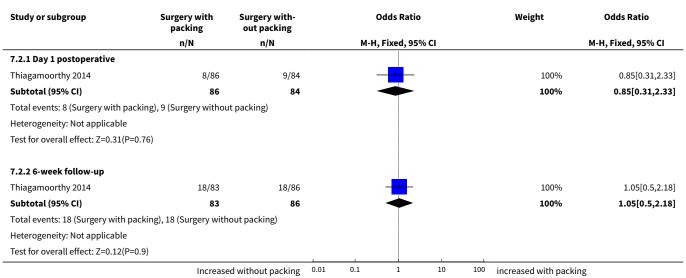
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Postoperative pelvic haematoma at 6 weeks	1	116	Odds Ratio (M-H, Fixed, 95% CI)	0.45 [0.13, 1.57]
2 Postoperative infection - urinary tract infection	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Day 1 postoperative	1	170	Odds Ratio (M-H, Fixed, 95% CI)	0.85 [0.31, 2.33]
2.2 6-week follow-up	1	169	Odds Ratio (M-H, Fixed, 95% CI)	1.05 [0.50, 2.18]
3 Postoperative infection - vaginal infection	1		Odds Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Day 1 postoperative	1	171	Odds Ratio (M-H, Fixed, 95% CI)	0.79 [0.31, 2.01]
3.2 6-week follow-up	1	169	Odds Ratio (M-H, Fixed, 95% CI)	0.59 [0.31, 1.14]



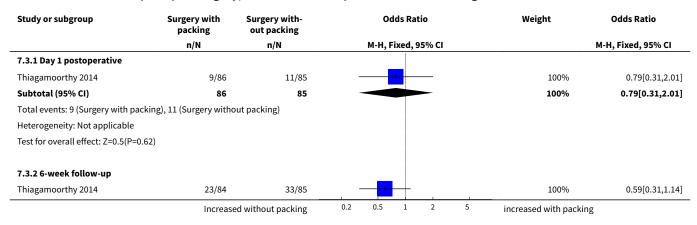
# Analysis 7.1. Comparison 7 Vaginal pack insertion after pelvic organ prolapse surgery, Outcome 1 Postoperative pelvic haematoma at 6 weeks.



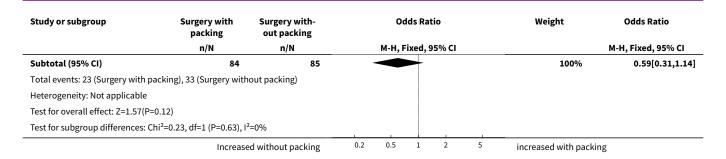
# Analysis 7.2. Comparison 7 Vaginal pack insertion after pelvic organ prolapse surgery, Outcome 2 Postoperative infection - urinary tract infection.



Analysis 7.3. Comparison 7 Vaginal pack insertion after pelvic organ prolapse surgery, Outcome 3 Postoperative infection - vaginal infection.



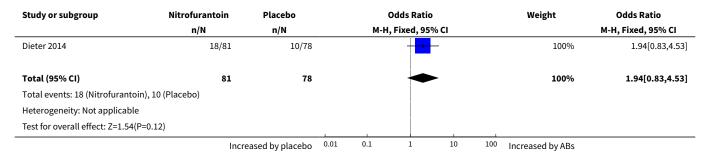




## Comparison 8. Prophylactic antibiotics for postoperative patients required urinary catheterisation

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Postoperative infection - UTI	1	159	Odds Ratio (M-H, Fixed, 95% CI)	1.94 [0.83, 4.53]

# Analysis 8.1. Comparison 8 Prophylactic antibiotics for postoperative patients required urinary catheterisation, Outcome 1 Postoperative infection - UTI.



# Comparison 9. No catheter vs SPC

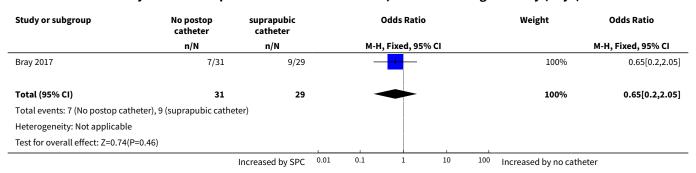
Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Urinary tract infection	1	60	Odds Ratio (M-H, Random, 95% CI)	0.18 [0.05, 0.60]
2 Length of stay (days)	1	60	Odds Ratio (M-H, Fixed, 95% CI)	0.65 [0.20, 2.05]



# Analysis 9.1. Comparison 9 No catheter vs SPC, Outcome 1 Urinary tract infection.

Study or subgroup	No postop catheter	suprapubic catheter		00	lds Ratio	•	Weight	Odds Ratio	
	n/N	n/N		M-H, Ra	ndom, 9	5% CI			M-H, Random, 95% CI
Bray 2017	5/31	15/29		-	-			100%	0.18[0.05,0.6]
Total (95% CI)	31	29		•	-			100%	0.18[0.05,0.6]
Total events: 5 (No postop catheter	), 15 (suprapubic cath	eter)							
Heterogeneity: Not applicable									
Test for overall effect: Z=2.8(P=0.01	)					1			
		Increased by SPC	0.01	0.1	1	10	100	Increased by no cathe	ter

## Analysis 9.2. Comparison 9 No catheter vs SPC, Outcome 2 Length of stay (days).



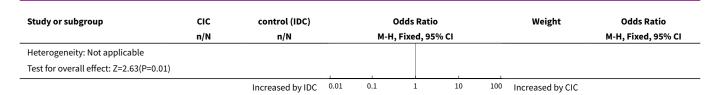
#### Comparison 10. CIC vs IDC

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Bacteriuria	1	83	Odds Ratio (M-H, Fixed, 95% CI)	0.24 [0.08, 0.69]
2 Urinary tract infection	1	78	Odds Ratio (M-H, Fixed, 95% CI)	0.19 [0.06, 0.62]
3 Number of patients who would choose the same treatment	1	87	Odds Ratio (M-H, Fixed, 95% CI)	1.26 [0.44, 3.65]

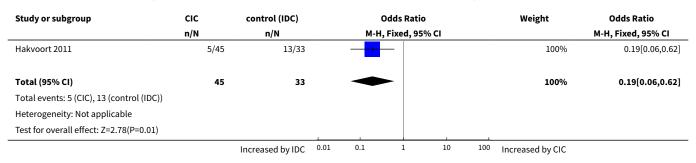
## Analysis 10.1. Comparison 10 CIC vs IDC, Outcome 1 Bacteriuria.

Study or subgroup	CIC	control (IDC)		Odd		Odds Ratio		Weight	Odds Ratio
	n/N	n/N		M-H, Fixed, 95		M-H, Fixed, 95% CI			M-H, Fixed, 95% CI
Hakvoort 2011	6/45	15/38		-	-			100%	0.24[0.08,0.69]
Total (95% CI)	45	38		•	-			100%	0.24[0.08,0.69]
Total events: 6 (CIC), 15 (control (IDC))						1			
		Increased by IDC	0.01	0.1	1	10	100	Increased by CIC	

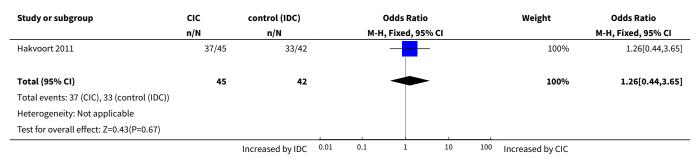




# Analysis 10.2. Comparison 10 CIC vs IDC, Outcome 2 Urinary tract infection.



## Analysis 10.3. Comparison 10 CIC vs IDC, Outcome 3 Number of patients who would choose the same treatment.



#### Comparison 11. Catheter removal POD vs POD 4

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Urinary tract infection	1	197	Odds Ratio (M-H, Fixed, 95% CI)	0.10 [0.04, 0.28]
2 Mean catheter days	1	197	Std. Mean Difference (IV, Fixed, 95% CI)	-2.17 [-2.53, -1.82]
3 Mean hospital stay (days)	1	197	Mean Difference (IV, Fixed, 95% CI)	-1.18 [-1.44, -0.92]
4 Repeat catheterisation	1	197	Odds Ratio (M-H, Fixed, 95% CI)	3.10 [1.30, 7.40]



## Analysis 11.1. Comparison 11 Catheter removal POD vs POD 4, Outcome 1 Urinary tract infection.

Study or subgroup	IDC re- moved POD 1				Odds Ratio	•		Weight	Odds Ratio	
	n/N	n/N		М-Н,	Fixed, 95	% CI			M-H, Fixed, 95% CI	
Kamilya 2010	5/98	34/99						100%	0.1[0.04,0.28]	
Total (95% CI)	98	99		•				100%	0.1[0.04,0.28]	
Total events: 5 (IDC removed POD	1), 34 (IDC removed PO	D 4)								
Heterogeneity: Not applicable										
Test for overall effect: Z=4.5(P<0.00	001)						1			
	Ir	creased by POD 4	0.01	0.1	1	10	100	Increased by POD 1		

## Analysis 11.2. Comparison 11 Catheter removal POD vs POD 4, Outcome 2 Mean catheter days.

Study or subgroup	IDC ren	noved POD 1	IDC removed POD 4			Std. M	ean Differe	nce		Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fix	ed, 95% CI				Fixed, 95% CI
Kamilya 2010	98	1.6 (1.3)	99	4.1 (0.9)		+				100%	-2.17[-2.53,-1.82]
Total ***	98		99			•				100%	-2.17[-2.53,-1.82]
Heterogeneity: Not applicable											
Test for overall effect: Z=12.05(P	<0.0001)										
			Increa	sed by POD 4	-5	-2.5	0	2.5	5	Increased	by POD 1

Analysis 11.3. Comparison 11 Catheter removal POD vs POD 4, Outcome 3 Mean hospital stay (days).

Study or subgroup	IDC removed POD 1		IDC ren	noved POD 4	Mean Difference		Weight		Mean Difference		
	N	Mean(SD)	N	Mean(SD)		Fi	xed, 95% CI				Fixed, 95% CI
Kamilya 2010	98	6.5 (0.9)	99	7.7 (1)		+				100%	-1.18[-1.44,-0.92]
Total ***	98		99			•				100%	-1.18[-1.44,-0.92]
Heterogeneity: Not applicable											
Test for overall effect: Z=8.9(P<0.000	1)										
			Increa	sed by POD 4	-4	-2	0	2	4	Increased b	v POD 1

Analysis 11.4. Comparison 11 Catheter removal POD vs POD 4, Outcome 4 Repeat catheterisation.

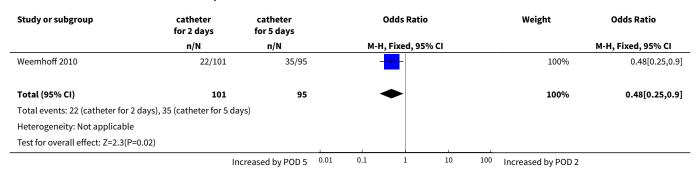
Study or subgroup	IDC re- moved POD 1	IDC re- moved POD 4		Odds Ratio			Weight	Odds Ratio	
	n/N	n/N		M-H	l, Fixed, 95%	CI			M-H, Fixed, 95% CI
Kamilya 2010	21/98	8/99			-	H		100%	3.1[1.3,7.4]
Total (95% CI)	98	99			•	<b>-</b>		100%	3.1[1.3,7.4]
Total events: 21 (IDC removed PC	DD 1), 8 (IDC removed PC	DD 4)							
Heterogeneity: Not applicable									
Test for overall effect: Z=2.55(P=0	0.01)								
	li	ncreased by POD 4	0.01	0.1	1	10	100	Increased by POD 1	



#### Comparison 12. Catheter removal POD 2 vs POD 5

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 UTI at the time of first catheter removal	1	196	Odds Ratio (M-H, Fixed, 95% CI)	0.48 [0.25, 0.90]
2 Patients needed temporary catheter replacement (events)	1	245	Odds Ratio (M-H, Fixed, 95% CI)	4.01 [1.93, 8.35]
3 Passed TOV and no UTI at time of first catheter removal	1	245	Odds Ratio (M-H, Fixed, 95% CI)	1.05 [0.62, 1.78]

# Analysis 12.1. Comparison 12 Catheter removal POD 2 vs POD 5, Outcome 1 UTI at the time of first catheter removal.



# Analysis 12.2. Comparison 12 Catheter removal POD 2 vs POD 5, Outcome 2 Patients needed temporary catheter replacement (events).

Study or subgroup	catheter for 2 days	catheter for 5 days			Odds Ratio	•		Weight	Odds Ratio
	n/N	n/N		М-Н	, Fixed, 95	% CI			M-H, Fixed, 95% CI
Weemhoff 2010	35/123	11/122			+	<del> </del>		100%	4.01[1.93,8.35]
Total (95% CI)	123	122			•	•		100%	4.01[1.93,8.35]
Total events: 35 (catheter for 2 da	ys), 11 (catheter for 5 da	ys)							
Heterogeneity: Not applicable									
Test for overall effect: Z=3.72(P=0	)								
	Inc	creased by POD 5	0.01	0.1	1	10	100	Increased by POD 2	



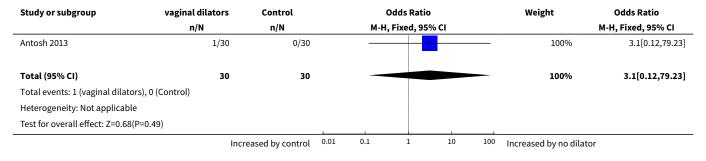
# Analysis 12.3. Comparison 12 Catheter removal POD 2 vs POD 5, Outcome 3 Passed TOV and no UTI at time of first catheter removal.

Study or subgroup	catheter for 2 days	catheter for 5 days		Odds Ratio		Weight	Odds Ratio	
	n/N	n/N		M-H, Fixed, 95%	% CI			M-H, Fixed, 95% CI
Weemhoff 2010	82/123	80/122		-			100%	1.05[0.62,1.78]
Total (95% CI)	123	122		•			100%	1.05[0.62,1.78]
Total events: 82 (catheter for 2	days), 80 (catheter for 5 day	rs)						
Heterogeneity: Not applicable								
Test for overall effect: Z=0.18(P=	=0.86)		1		1			
	Inc	reased by POD 5	0.01	0.1 1	10	100	Increased by POD 2	

# Comparison 13. Use of vaginal dilators postoperatively

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Postoperative mesh exposure	1	60	Odds Ratio (M-H, Fixed, 95% CI)	3.10 [0.12, 79.23]
2 Urinary tract infection	1	60	Odds Ratio (M-H, Fixed, 95% CI)	4.26 [0.81, 22.53]
3 PGI-I at 6 months	1	52	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.63, 0.03]
4 Vaginal calibre	1	49	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-0.93, 0.53]
5 PisQ	1	50	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-2.92, 2.52]
6 PisQ Question 5	1	50	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.89, 0.29]
7 De novo dyspareunia	1	50	Odds Ratio (M-H, Fixed, 95% CI)	3.57 [0.35, 36.94]

Analysis 13.1. Comparison 13 Use of vaginal dilators postoperatively, Outcome 1 Postoperative mesh exposure.





# Analysis 13.2. Comparison 13 Use of vaginal dilators postoperatively, Outcome 2 Urinary tract infection.

Study or subgroup	vaginal dilators	Control			Odds Ratio	•		Weight	Odds Ratio
	n/N	n/N		М-Н	, Fixed, 95	% CI			M-H, Fixed, 95% CI
Antosh 2013	7/30	2/30			+	-		100%	4.26[0.81,22.53]
Total (95% CI)	30	30				<b>-</b>		100%	4.26[0.81,22.53]
Total events: 7 (vaginal dilat	ors), 2 (Control)								
Heterogeneity: Not applicab	le								
Test for overall effect: Z=1.71	L(P=0.09)					1	1		
	Incr	eased by control	0.01	0.1	1	10	100	Increased by no dilator	•

## Analysis 13.3. Comparison 13 Use of vaginal dilators postoperatively, Outcome 3 PGI-I at 6 months.

Study or subgroup	vagin	al dilators	c	ontrol		Me	an Differenc	:e		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		F	ixed, 95% CI	I			Fixed, 95% CI
Antosh 2013	25	1.4 (0.5)	27	1.7 (0.7)						100%	-0.3[-0.63,0.03]
Total ***	25		27							100%	-0.3[-0.63,0.03]
Heterogeneity: Not applicable											
Test for overall effect: Z=1.79(P=0.07)					1						
			Increas	ed by control	-100	-50	0	50	100	Increased b	y no dilator

## Analysis 13.4. Comparison 13 Use of vaginal dilators postoperatively, Outcome 4 Vaginal calibre.

Study or subgroup	vagin	al dilators	С	ontrol		Me	an Differen	ce		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		F	ixed, 95% C	:1			Fixed, 95% CI
Antosh 2013	24	3.9 (1.2)	25	4.1 (1.4)						100%	-0.2[-0.93,0.53]
Total ***	24		25							100%	-0.2[-0.93,0.53]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.54(P=0.59)											
			Increas	ed by control	-100	-50	0	50	100	Increased b	y no dilator

## Analysis 13.5. Comparison 13 Use of vaginal dilators postoperatively, Outcome 5 PisQ.

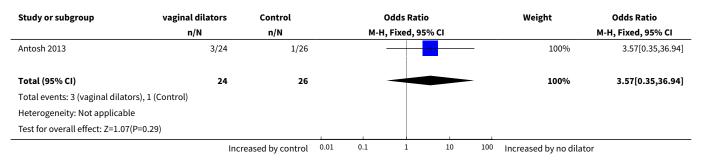
Study or subgroup	vagin	al dilators	c	ontrol		Me	an Difference	•		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		F	ixed, 95% CI				Fixed, 95% CI
Antosh 2013	24	37.3 (4.4)	26	37.5 (5.4)			+			100%	-0.2[-2.92,2.52]
Total ***	24		26				•			100%	-0.2[-2.92,2.52]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.14(P=0.89)					1						
			Increas	ed by control	-100	-50	0	50	100	Increased b	y no dilator



#### Analysis 13.6. Comparison 13 Use of vaginal dilators postoperatively, Outcome 6 PisQ Question 5.

Study or subgroup	vagin	al dilators	С	ontrol		Me	an Differenc	e		Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)		Fi	ixed, 95% CI				Fixed, 95% CI
Antosh 2013	24	2.8 (1.2)	26	3.1 (0.9)						100%	-0.3[-0.89,0.29]
Total ***	24		26							100%	-0.3[-0.89,0.29]
Heterogeneity: Not applicable											
Test for overall effect: Z=0.99(P=0.32)											
			Increas	ed by control	-100	-50	0	50	100	Increased b	y no dilator

Analysis 13.7. Comparison 13 Use of vaginal dilators postoperatively, Outcome 7 De novo dyspareunia.



#### **ADDITIONAL TABLES**

Table 1. Pelvic floor muscle training

	Intervention	Visits	Providers	Follow-up	
Barber 2014	Individualised programme	1 preoperative visit and visits at	Clinicians trained	24 months	
	BMPT (behavioural therapy with pelvic floor muscle training)	2, 4, 6, 8, and 12 weeks postoperatively	and certified in BMPT after undergoing centralised training		
McClurg 2014	Individualised programme	1 preoperative visit and 6 post-	Women's health	12 months	
	PFMT (pelvic floor muscle training)	operative visits during 18 weeks	physiotherapists		
Pauls 2013	Individualised programme	1 preoperative visit and visits at	Physiotherapists	12 weeks	
	PFMT (pelvic floor muscle training)	2, 4, 6, 8, and 12 weeks postoperatively			

#### Interventions (full description):

Barber 2014: the intervention group received behavioural therapy with pelvic floor muscle training (BPMT): an individualized programme. Patients were educated on individualised progressive pelvic floor muscle exercise and behavioural strategies to reduce urinary and colorectal symptoms. Education was provided by clinicians with varying degrees of BPMT experience who had undergone centralised training.

McClurg 2014: the intervention group received perioperative PFMT (pelvic floor muscle training) by a women's health physiotherapist. At a preoperative appointment, a standardised history was taken. Anatomy and function of pelvic floor muscles (PFMs) were discussed and types of prolapse described using diagrams and a model of the pelvis. Women were taught (by digital palpation) how to correctly contract



their PFMs and how to precontract against increases in intra-abdominal pressure. At this visit, women were advised to do three sets of ten maximum contractions (up to 10-second hold) per day with 4-second rest between sets, followed by a 1-minute rest followed by ten fast contractions. During the first outpatient session (at week 6), a repeat vaginal examination assessed participants' ability to contract their PFMs. Five further weekly physiotherapy outpatient appointments within a period of 12 weeks were provided. An individualised home exercise programme was prescribed, with progression dictated by improvement in PFM function; physiotherapists were allowed to use adjuncts such as biofeedback, electrical stimulation, and exercise balls, as per their usual practice. Symptom changes, compliance with lifestyle advice, and changes in PFM strength were recorded at each subsequent consultation.

Pauls 2013: the intervention group underwent a physical therapy appointment 2 weeks before the scheduled surgery date. Appointments thereafter occurred at 2, 4, 6, 8, and 12 weeks postoperatively. As a component of their physical therapy sessions, participants received educational information and training regarding pelvic floor exercises and relaxation. Sessions were designed to encompass teaching regarding bladder and bowel function, pain management, breathing and relaxation, core exercises, and scar tissue mobilisation. Increased strengthening and training over time was outlined in the curriculum.

#### **APPENDICES**

#### Appendix 1. General Health Short Form Health Survey

General health Short Form Health Survey (SF-12): This form includes two questions on physical functioning, two questions on role limitations due to physical health problems, one question on bodily pain, one question on general health perceptions, one question on vitality (energy/fatigue), one question on social functioning, two questions on role limitations due to emotional problems, and two questions on general mental health (psychological distress and psychological well-being). Participants scoring ≥ 50 are considered to have better than average health. Those with scores < 50 represent less than average quality of life due to the participant's medical condition.

#### Appendix 2. Pelvic floor muscle (PFM) power or strength

Pelvic floor muscle (PFM) power or strength can be assessed by the Brink grading system (evaluates three pelvic floor muscle contraction variables) for the following.

- · Vaginal pressure or muscle force.
- Elevation or vertical displacement of the examiner's fingers.
- · Duration of contraction.

Each muscle contraction variable is rated on a four-point ordinal scale (FitzGerald 2007).

#### Appendix 3. Pelvic floor distress inventory

Pelvic Floor Distress Inventory - PFDI 20

Patient Name:

Date:

PFDI-20 Instructions: Please answer all questions in the following survey. These questions will ask if you have certain bowel, bladder, or pelvic symptoms, and if you do, how much they bother you. Answer these questions by circling the appropriate number. While answering these questions, please consider your symptoms over the past three months.

The PFDI-20 includes 20 items and three scales for rating your symptoms. All items use the following format with a response scale from 0 to 4.

Symptoms Present = YES, scale of bother

1 = not at all (experienced previously)	
2 = somewhat	
3 = moderately	
4 = quite a bit	



Symptoms Not Present = NO

0 = not present (never experienced)

Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6)

Do you	No	Yes
Usually experience pressure in the lower abdomen?	0	1234
2. Usually experience heaviness or dullness in the pelvic area?	0	1234
3. Usually have a bulge or something falling out that you can see or feel in your vaginal area?	0	1234
4. Ever have to push on the vagina or around the rectum to have or complete a bowel movement?	0	1234
5. Usually experience a feeling of incomplete bladder emptying?	0	1234
6. Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	0	1234

Colorectal-Anal Distress Inventory 8 (CRAD-8)

Do you(if Yes is your answer, how much does that bother you)	No	Yes
7. Feel you need to strain too hard to have a bowel movement?	0	1234
8. Feel you have not completely emptied your bowels at the end of a bowel movement?	0	1234
9. Usually lose stool beyond your control if your stool is well formed?	0	1234
10. Usually lose stool beyond your control if your stool is loose?	0	1234
11. Usually lose gas from the rectum beyond your control?	0	1234
12. Usually have pain when you pass your stool?	0	1234
13. Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	0	1234
14. Does part of your bowel ever bulge outside the rectum during or after a bowel movement?	0	1234



## Urinary Distress Inventory 6 (UDI-6)

Do you	No	Yes
15. Usually experience frequent urination?	0	1234
16. Usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	0	1234
17. Usually experience urine leakage related to coughing, sneezing, or laughing?	0	1234
18. Usually experience small amounts of urine leakage (i.e. drops)?	0	1234
19. Usually experience difficulty emptying your bladder?	0	1234
20. Usually experience pain or discomfort in the lower abdomen or in the genital region?	0	1234

## WHAT'S NEW

Date	Event	Description
22 April 2018	New search has been performed	Comparison of perioperative interventions in pelvic organ pro- lapse surgery was formerly part of the 2013 Cochrane systematic review titled "Surgical management of pelvic organ prolapse in women". We now present this as a separate systematic review.
22 April 2018	New citation required and conclusions have changed	12 studies have been added to the 2018 review: Adelowo 2017; Antosh 2013; Ballard 2014; Barber 2014; Billquist 2017; Bray 2017; Chan 2014; Dieter 2014; Henn 2016; McClurg 2014; Pauls 2013; Thiagamoorthy 2014. The addition of new studies and more specific focus in this update have led to changes to the conclusions of this review.

## HISTORY

Protocol first published: Issue 1, 2003 Review first published: Issue 8, 2018

Date	Event	Description
14 April 2010	Amended	Changed citation; added conflicts
17 November 2009	New citation required but conclusions have not changed	Full reports of 59 potentially eligible studies were assessed; for this update, 23 new eligible studies were assessed (Al-Nazer 2007a; Ali 2006a; Allahdin 2008; Barber 2006; Biller 2008; Borstad 2008; Braun 2007a; Carramao 2008a; Constantini 2008; de Tayrac 2008; Dietz 2008a; Glavind 2007; Guerette 2006a; Lim 2007a;



Date	Event	Description
		Meschia 2007a; Natale 2007; Natale 2009; Nguyen 2008; Nieminen 2008; Pantazis 2008a; Schierlitz 2007a; Segal 2007; Sivaslioglu 2008). Overall, 17 studies were excluded from the reviewsix during this update (Barber 2006; Biller 2008; Carramao 2008a; Glavind 2007; Meschia 2007a; Segal 2007). Full details are given in the "Characteristics of excluded studies" table.
		To this, the second update, 18 new trials were added (Al-Nazer 2007; Ali 2006; Allahdin 2008; Borstad 2008; Braun 2007a; Constantini 2007; Constantini 2008; de Tayrac 2008; Dietz 2008a; Guerette 2006; Lim 2007; Natale 2007; Natale 2009; Nguyen 2008; Nieminen 2008; Pantazis 2008; Schierlitz 2007; Sivaslioglu 2008) and 3 previously included studies were updated (Brubaker 2008; Meschia 2007; Roovers 2004).
9 February 2009	New search has been performed	New search February 2009
10 October 2008	Amended	Converted to new review format
17 April 2007	New citation required and conclusions have changed	Substantive Update, Issue 3, 2007. 22 RCTs (8 new included trials). Findings are still insufficient to provide robust evidence to support current and new practice (such as whether to perform a concurrent continence operation, or to use mesh or grafts).

#### **CONTRIBUTIONS OF AUTHORS**

All review authors contributed to writing the protocol. Five review authors (N Haya, C Maher, C Schmid, K Baessler, B Feiner) assessed the relevance and eligibility of studies for inclusion in the review. They then assessed the quality of included studies. Two review authors (from N Haya, B Feiner, and C Maher) independently extracted data from trial reports, interpreted the results, and contributed to the writing of the draft version of this review. All review authors read and approved the final draft.

## **DECLARATIONS OF INTEREST**

Nir Haya: no known conflict of interest.

Christopher Maher: no known conflict of interest.

Kaven Baessler: no known conflict of interest.

Corina Christmann-Schmid: no known conflict of interest.

Benjamin Feiner: no known conflict of interest.

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#### **Internal sources**

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Cochrane Review Support Programme: pelvic organ prolapse reviews

#### **External sources**

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#### INDEX TERMS

# **Medical Subject Headings (MeSH)**

Antibiotic Prophylaxis; Exercise; Imagery, Psychotherapy; Pelvic Floor; Pelvic Organ Prolapse [\*surgery]; Perioperative Care [\*methods]; Pessaries [statistics & numerical data]; Randomized Controlled Trials as Topic; Recurrence; Reoperation [statistics & numerical data]; Stents; Vasoconstrictor Agents [administration & dosage]

#### **MeSH check words**

Female; Humans